United States District Court, District of Nebraska

PONCA TRIBE OF NEBRASKA

Plaintiff,

v.

1. **MCKESSON CORPORATION;**
2. **CARDINAL HEALTH, INC.;**
3. **AMERISOURCEBERGEN CORP.;**
4. **WALGREENS BOOTS ALLIANCE, INC.;**
5. **CVS HEALTH CORP.;**
6. **PURDUE PHARMA L.P.;**
7. **PURDUE PHARMA, INC.;**
8. **THE PURDUE FREDERICK COMPANY, INC.;**
9. **CEPHALON, INC.;**
10. **TEVA PHARMACEUTICAL INDUSTRIES, LTD.;**
11. **TEVA PHARMACEUTICALS USA, INC.;**
12. **JOHNSON & JOHNSON;**
13. **JANSSEN PHARMACEUTICALS,INC.;**
14. **ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.;**
15. **JANSSEN PHARMACEUTICA INC. n/k/a JANSSEN PHARMACEUTICALS, INC.;**
16. **ENDO HEALTH SOLUTIONS INC.;**
17. **ENDO PHARMACEUTICALS, INC.;**
18. **INSYS THERAPEUTICS, INC.;**
19. **ALLERGAN PLC f/k/a ACTAVIS PLC;**
20. **WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.;**
21. **WATSON LABORATORIES, INC.;**
22. **ACTAVIS LLC;**
23. **ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.,**
24. **MALLINCKRODT PLC,**
25. **MALLINKRODT PHARMACEUTICALS,**

Defendants.

No: _____

Complaint

And

Demand for

Trial by Jury

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Trial Location Designation

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Complaint & Jury Demand

Plaintiff alleges:

Overview

1. The Ponca Tribe of Nebraska ("Ponca Tribe") is a federally recognized Indian Tribe (P.L. 101-484) whose business affairs are conducted by its Ponca Tribal Counsel as approved in the Constitution approved July 22, 1994 by the Acting Deputy Commissioner of Indian Affairs. The Ponca Tribe has a proud, distinguished history of the long and tortured effort for recognition of civil rights, sovereignty, and treaty observance. Its distinguished Chief Standing Bear was the first Native American to be recognized as a human being under the Constitution and laws of the United States. Supported by his entire Ponca Tribe, Chief Standing Bear won this recognition upon uttering these famous words before a United States District Judge in a habeas corpus proceeding: "*I am a Man.*"

2. For the first time, in 1879 (14 years after the Civil War ended) the Court declared that Native Americans were recognized as human beings and protected by the Constitution. Before then, members of the Ponca, and all other Tribes were disregarded from censuses, and denied all protections of the law. In the *Standing Bear* case, the Court halted the practice of "relocating" Native Americans in forced marches from their homes to reservations.[1] It did so because Chief Standing Bear and his people stood up, stepped forward, and spoke out. Now, they do so against the Defendants, here.

[1] Trial of Chief Standing Bear, *U.S. v. Crook,* 25 F Cas 695 (D Neb 1879)(Unfortunately, the famous statement was reported widely in the press but not quoted by Court in its extraordinarily important opinion).

3. The Ponca Tribe sues for damages and injunctive relief because the Defendants manufactured[2], marketed, and distributed[3] in commerce opioid medications[4] without proper controls to assure delivery to informed hospitals, physicians and other licensed providers, and their patients, and to political subdivisions providing public health services and inmate services to person in detention.

4. The Ponca Tribe has a duly approved Constitution[5] adopted June 24, 1994 as authorized by Section 16 of the *Indian Reorganization Act of 1934* (48 Stat 984). The Ponca Tribe does not have a reservation but its members are entitled to all rights, privileges, services and benefits furnished to federally recognized tribes.[6] The Ponca Tribe has defined service areas in South Dakota, Nebraska, Iowa and elsewhere.

5. The Ponca Tribe of Nebraska is a sovereign government and is recognized by the United States of America as a sovereign under the *Ponca Tribe of Nebraska Restoration of Rights & Privileges Act*.[7] It provides these government services: a) Health services at two primary health and wellness centers in Omaha NE and Norfolk NE and multiple secondary health services; b) Dental services at its two primary health service locations; c) Behavioral Health services including drug and alcohol counseling, individual and family counseling, and youth prevention services at four Nebraska locations and one Iowa location; d) Health advocacy and at home support at four

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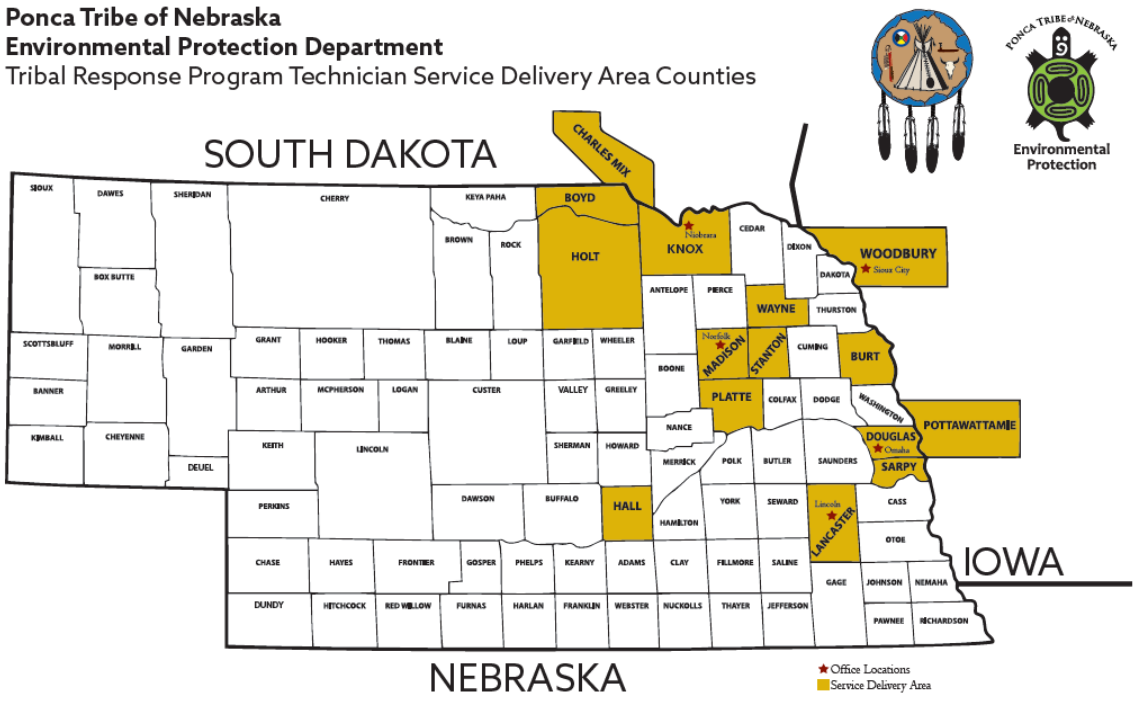
2 "Manufacturer" is a term defined at 21 CFR § 803.3(l).
3 "Distributor" is a term defined at 21 CFR § 803.3(e).
4 Partial list of opioid medications at https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm251735.htm
5 https://www.poncatribe-ne.org/tribal-documents/
6 25 USC § 983c. Available at ttps://www.gpo.gov/fdsys/pkg/USCODE-2011-title25/html/USCODE-2011-title25-chap14-subchapXLVI-A.htm
7 25 USC Ch 14 Sub ch XLVI-A, 25 USC §§ 983 et seq. available at

Nebraska locations; e) a Special Diabetes Program following the IHS Standards of Care for the Treatment of People Living with Diabetes; and, f) Programs for Purchased / Referred Care for those in need of such services. The Tribe provides: g) Environmental Protection Dept services to promote, maintain and protect the health and welfare of Tribal Members and the environment with operations in these locations:



6. The Ponca Tribe has land in South Dakota, Iowa and Nebraska held in trust for its benefit by the United States in these areas as defined by the *Ponca Restoration Act*:

State	**Counties**
Nebraska	Boyd, Holt, Douglas, Hall, Holt, Knox, Lancaster, Madison, Platte, Sarpy, Stanton and Wayne
South Dakota	Charles Mix
Iowa	Pottawattomie , Woodbury

The Tribe supplies judicial services, legal assistance, and related law enforcement services. It also provides housing and the services of its Housing Authority Board. The Tribe has standing to sue.[8]

Jurisdiction; Venue; Parties

7. The Court has subject matter jurisdiction pursuant to 28 USC § 1331 (federal question jurisdiction) and § 1332 (diversity jurisdiction). The actual amount in controversy exceeds $75,000, exclusive of costs and attorneys' fees.

8. Venue is proper in the District of Nebraska pursuant to 28 USC § 1392(b)(2). A substantial part of activity giving rise to these claims occurred in Nebraska.

9. Each Defendant conducted extensive business in Nebraska and most sold goods to The Tribe's health service and other health services providing care for the Ponca Tribe and its Nebraska and other health services. Each Defendant contracted, delivered goods and services, and caused tortious injury and damages in this State. By committing torts in Nebraska, each Defendant is subject to the personal jurisdiction of the U.S. District Court in this Nebraska.

General Allegations

10. The United States faces a public health crisis arising from the profligate manufacturing, distribution, permissive and knowing diversion, and abuse of opioids and opioids medications. An opioid addiction epidemic[9] has resulted. The epidemic poses multiple threats. These include a) deaths in the Native American population and in The

[8] *25 USC* § 983(g) & Ponca Tribe of Neb Const Art V.

[9] On October 26, 2017 the President of United States declared the opioid epidemic a national public health emergency. Press release, President of the United States, www.whitehouse.gov/briefings-statements/president-donald-j-trump-taking-action-drug-addiction-opioid-crisis/.

Ponca Tribe at rates in excess of the number killed by automobile collisions annually; b) demands on tribal public health systems so extensive and costly as to challenge, and potentially defeat, the capacity of those systems to provide services to persons with other needs; c) to cause such havoc and destruction in the lives of addicts, and persons in recovery, as to decimate productivity; and, leave the Ponca Tribe, and America, with generations of persons unable to provide for their own needs.

11. Defendants' liability is based on historical facts and actions summarized below. Each Defendant participated in this conduct. Relevant terms and affected non-party organizations involved in this case include:

11.1. Opioid [10] medications [11] are manufactured by some Defendants and distributed by others in quantities in excess of levels needed, and placed in distribution so excess inventories are stored in the hands of distributors, pharmacists, physicians, hospitals, or other providers.

11.2. Opioid medications are, or have been, manufactured under circumstances that are dangerous due to inadequate or misrepresented testing and risks upon distribution and under circumstances in which the medications were placed in the stream of commerce with these risks.

11.3. Opioids, including opioid medications, are "controlled substances" and "drugs" and "narcotic drugs" and their foreseeable adulteration after

[10] "Opioids" "are a class of drugs used to reduce pain". https://www.cdc.gov/drugoverdose/opioids/index.html

[11] "Opioid medications" are described by the U.S. FDA as "Prescription opioids are powerful pain-reducing medications that include prescription oxycodone, hydrocodone and morphine, among others, and have both benefits as well as potentially serious risks. These medications can help manage pain when prescribed for the right condition and when used properly. But when misused or abused, they can cause serious harm, including addiction, overdose and death." https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm337066.htm

diversion due to Defendants' wrongful acts creates "counterfeit substances" all as defined by, and used in Nebraska law.[12] They also include "opiates" as defined by Nebraska law.[13] Defendants repeatedly violated the provisions of Nebraska's *Uniform Controlled Substances Act* as demonstrated by the allegations below and have made themselves subject to regulatory discipline in Nebraska.[14]

11.4. Opioid medications are and have been distributed and marketed in connection with a variety of abusive, misleading, false strategies to purport to "normalize" the prescription and use of opioids for patients, and to deliberately falsify experiences, outcomes, patient acceptance, and benefits of opioids for the purpose, or with the effect, of altering perceptions of medical practitioners across the United States and to the Tribe and members, to change the generally accepted "standard of care" for opioid usage in the medical community.[15]

11.5. Opioid medications are and have been distributed and marketed through and with the purported endorsements of organizations or bodies represented as neutral medical boards, foundations or groups that purported to establish guidelines to promote liberal and excessive use of opioid medications for

[12] *Nebraska Uniform Controlled Substances Act, Neb Rev Stat* § 28-401 et seq.
[13] *Neb Rev Stat* § 28-401 (4)(5)(11)(15)(16) (definitions).
[14] *Neb Rev Stat* § 28-409.
[15] Compliance with government regulations or industry standards does not prove that the standard of care is met. 10 Bus & Comm'l Litig in Fed Cts. § 103.79 (ABA 4th Ed) (WL Updated Nov 2017).

patients presenting with pain.[16] These false organizations included but were not limited to:

Federation of State Medical Board Examiners ("FSMBA"), a national trade group representing 70 medical and osteopathic boards across the United States. FSMB describes itself as: "FSMB supports America's state medical boards in licensing, disciplining and regulating physicians and other healthcare professionals. Our end goal: keep patients safe."[17]

The Joint Commission, an organization that establishes standards for treatment and accredits nearly 21,000 healthcare organizations and programs in the United States, and declares that its "vision statement" is "all people always experience the safest, highest quality, best-value health care across all settings."[18]

American Pain Foundation ("APF"), was a front organization for some or all Defendants that described itself as the nation's largest organization for pain patients, and which publishes guidelines and treatment options which exaggerate the benefits and understate the risks and dangers of opioids.[19]

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[16] One Defendant, Purdue Pharma L.P. admitted these kinds of actions and others referred to in this Complaint in Assurance of Discontinuance No. 15-151 under Executive Law § 63. Subd 15, in August 2015. Accessible at https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-purdue-pharma-ensures-responsible-and-transparent

[17] https://www.fsmb.org/

[18] https://www.jointcommission.org/about_us/about_the_joint_commission_main.aspx

[19] APF shut down its operation when investigated by the United States Senate for its inappropriate ties to the pharmaceutical industry. It declared abrupt cessation of its existence on or about May 8, 2012. *nationalpainreport.com/american-pain-foundation-calls-it-quits-8814140.html*

National Initiative on Pain Control ("NIPC"), was a front organization for some or all Defendants developed by APF which operated a now defunct website.[20]

American Academy of Pain Medicine, ("AAPM") became a front organization for some or all Defendants. It describes itself as "the Voice of Pain Medicine", engages in "advocacy efforts" through lobbyists and others, purports to sponsor or report on medications, and purports to sponsor and promote objective Continuing Medical Education ("CME") programming. AAPM describes itself as "the medical specialty society representing physicians practicing in the field of pain medicine. As a medical specialty society, the Academy is involved in education, training, advocacy, and research in the specialty of pain medicine." [21]

American Pain Society ("APS"), describes itself as **"**a multidisciplinary community [of] diverse group of scientists, clinicians, and other professionals to increase the knowledge of pain and transform public policy and clinical practice to reduce pain related suffering."[22] But, APS became and was used as a front organization for some or all Defendants. AAPM and APS acted collaboratively to issue Guidelines in 2009 recommending use of opioids to treat chronic pain.[23] However, 14 of 21 Board members

[20] www.painknowledge.org
[21] http://www.painmed.org/
[22] http://americanpainsociety.org/about-us/overview
[23] Roger Chou, et al., Clinical Guidelines for Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain, 10(2) J Pain 113 (2009).

who participated in the 2009 Guidelines received funding from defendants Purdue, Endo, Cephalon, Janssen or others. These Guidelines falsely promoted opioids as safe.

Others. Discovery is required to identify other front groups.

12. Defendants paid individual physicians and other persons influential in medical communities, generally in the form of consulting and speaking fees and gifts or discount coupons to speak on their behalf and endorse their opioid products as safe, effective and broadly used. The recruited persons were called, by the Defendants, "Key Opinion Leaders" or "KOLs".[24] They were recruited to receive gifts, undergoing indoctrination and then repeat the messages of Defendants to promote opioid use, overstate perceived advantages, and understate or misstate dangers, risks, addictive qualities, and morbidities associated with use of the drugs. This is widely known in the medical community, and has been documented as well.[25] All or nearly all Defendants engaged in this activity.

13. Defendants engaged in false and deceptive statements acts and practices designed to mislead a) medical practitioners[26] about the safety, efficacy, and general acceptance of opioid medications, and b) members of the public who were potential users

[24] Payments were admitted in a June 8, 2012 Letter from Federation of State Medical Boards to U.S. Senators Max Baucus and Charles Grassley.

[25] For one example, see, Lynette Reid & Matthew Herder, *The Speakers' bureau system: a form of peer selling*, 7(2) Open Med. e31-e39 (Apr. 2, 2013), https://www.ncbi.nlm.nih.gov/pmc/articles/ PMC3863750/).

[26] Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain –Misconceptions and Mitigation Strategies*, 374 New Eng. J. Med. 1253-63 (Mar. 31, 2016), http://www.nejm.org/doi/full/10.1056/NEJMra1507771#t=article).

that opioid medications were safe and effective.[27] Each Defendant participated in this conduct or assented to it.

14. Defendants misrepresented the state of medical and scientific studies and data about the safety, efficacy, and general acceptance of opioid medications directly and through surrogates in public statements though they knew this was false or recklessly disregarded the truth.[28]

15. Defendants failed to identify or disclose diversion of opioids from intended recipients or responsible licensed dispensaries and practitioners, and failed to track diversion and identify it as required by law.[29] . Defendants concocted and promoted the concept of a medical condition of "pseudo-addiction". They misstated and minimized difficulties of becoming disconnected when addicted.[30] Each Defendant participated in this conduct or assented to it.

16. Defendants misrepresented incidences of mortality and morbidity while nearly 183,000 persons are believed to have died of opioids between 1999 and 2015 making this is widely known as the worst public health epidemic in the United States' history.[31] Epidemic data and statistics are compiled and were falsely presented.[32]

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[27] Fn 8, above. Anna Lembke, *Drug Dealer, MD: How Doctors Were Duped, Patients Got Hooked, and Why It's So Hard to Stop* 18 (Johns Hopkins University Press 2016). "'[U]nintentional poisoning deaths' from prescription opioids quadrupled between 1999 and 2010, outnumbering deaths from heroin and cocaine combined."

[28] *Agency for Healthcare Research and Quality (US): The Effectiveness and Risks of Long-Term Opioid Treatment of Chronic Pain*, Evid. Rep./Tech. Assess., No. 218 (2014), https://ahrq-ehcapplication.s3.amazonaws.com/media/pdf/chronic-pain-opioid-treatmentresearch.pdf)).

[29] Nora D Volkow et al, *Curtailing Diversion & Abuse of Opioid Analgesics Without Jeopardizing Pain Treatment*, 305(13) JAMA 1346 (2011).

[30] Scott M. Fishman, *Responsible Opioid Prescribing: A Physician's Guide* 8-9 (Waterford Life Sciences 2007).

[31] *Baker et al., The Worst Drug Epidemic in US History*, The Journal of Global Drug Policy & Practice, *www.globaldrugpolicy.org/.../The%20Worst%20Drug%20Epidemic%20in%20US%2...*

[32] U.S. Dept of Health & Human Services, *About the U.S. Opioid Epidemic, https://www.hhs.gov/opioids/about-the-epidemic/*; USC Annenberg, Reporting on America's Opioid Crisis Center for Health Journalism,

17. Defendants committed other acts and omissions yet to be discovered.[33]

18. Opioids are distributed without manufacturer or distributor controls sufficient to keep them from diversion to persons who should not have them. This is so common that opioid medications have street names. These are among the most common brand names and street names of common opioids[34]:

BRAND NAMES: Fiorional with Codeine Robitussin A-C Tylenol with Codeine Empirin with Codeine Roxanol Duramorph Demerol.	**STREET NAMES**: Captain Cody Schoolboy Doors & Fours Pancakes & Syrup Loads M Miss Emma Monkey White Stuff Demmies Pain killer.
BRAND NAMES: Actiq Duragesic Sublimaze Oxycontin Percodan Percocet Tylox Dilaudid.	**STREET NAMES:** Oxy 80 Oxycat Hillbilly Heroin Percs Perks Juice Dillies.
BRAND NAME: Fentanyl or fentanyl transmural	**STREET NAME:** Fentanyl Apache China Girl Dance Fever Goodfella Murder 8 Tango & Cash China White Friend Jackpot TNT

Defendants

19. The Defendants are manufacturers and distributors of opioid controlled medications who acted in common, and, at times, in concert to place opioids in the hands of medical care providers, and in the bodies of persons in Nebraska but failed to protect Nebraska residents from diversion, abuse, mal-distribution, and misdirection of the opioids to innocent victims including persons served by Plaintiff.

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https://www.centerforhealthjournalism.org/content/reporting-americas-opioid-drug-crisis A compilation of articles may be found at *https://publicadmin.usc.edu/blog/opioids-the-worst-drug-crisis-in-history/*

[33] See, e.g., Press Release, U.S. Attorney, W.D. VA Statement of U.S. Attorney John Brownlee on the Guilty Plea of the Purdue Frederick Co. and Its Executives for Illegally Misbranding Oxycontin (May 10, 2007), https://assets.documentcloud.org/ documents/279028/purdue-guilty-plea.pdf).

[34] https://www.drugfreeworld.org/drugfacts/prescription/opioids-and-morphine-derivatives.html

20. Defendants are required to comply with licensure and registration criteria of the Drug Enforcement Diversion Control Division of the U.S. Department of Justice Drug Enforcement Administration.[35] They may have registered, but have not complied with Diversion Control requirements.

Distributor Defendants

McKesson, Cardinal, AmerisourceBergen, and Teva Pharmaceutical Industries, Ltd., are collectively referred to hereinafter as "Distributor Defendants."

20.1. **Defendant McKesson Corporation** ("McKesson" or "Distributor Defendant") has its principal place of business at One Post St., San Francisco, California 94104 and is incorporated under the laws of Delaware.[36] During all relevant times, McKesson has distributed substantial amounts of prescription opioids to providers and retailers in the State of Nebraska. Until 2016, McKesson had office locations and a distribution center in La Vista, Sarpy County, Nebraska.

20.2. **Defendant Cardinal Health, Inc.** ("Cardinal") has its principal place of business at 7000 Cardinal Place, Dublin OH 43107, and is incorporated under the laws of Ohio.[37] During all relevant times, Cardinal has distributed substantial amounts of prescription opioids to providers and retailers in the State of Nebraska and has distributed or directed distribution from Nebraska.

[35] Application forms, summary of requirements, Schedules listing Drugs accessible at https://www.deadiversion.usdoj.gov/drugreg/reg_apps/225/225_instruct.htm#3b

[36] http://investor.mckesson.com/sites/mckesson.investorhq.businesswire.com/files/report/file/2017_McKesson_Annual_Report_0.pdf

[37] https://www.sec.gov/Archives/edgar/data/721371/000095015207007107/l27624ae10vk.htm

20.3. **Defendant AmerisourceBergen Corporation** has its principal place of business at 1300 Morris Drive, Chesterbrooke, PA 19087-5594 and is incorporated under the laws of Delaware.[38] During all relevant times, AmerisourceBergen has distributed substantial amounts of prescription opioids to providers and retailers in Nebraska.

20.4. **The Teva Defendants** are described below. They are also manufacturers and distribution activities and companies.

Pharmacy Defendants

Walgreens Boots Alliance, Inc. and CVS Health Corporation are referred to hereinafter as the "Pharmacy Defendants."

20.5. **Defendant Walgreens Boots Alliance, Inc.** ("Walgreens") has its principal place of business at 108 Wilmot Road, Deerfield, Illinois and is incorporated under the laws of Illinois.[39] Walgreens conducts retail pharmacy business at approximately 20 business locations in Nebraska with additional locations in or near Plaintiff's service areas in South Dakota and Iowa.[40] Walgreens retail pharmacies sold and distributed opioid prescriptions to persons served by Plaintiff in Plaintiff's service areas. These persons filled opioid prescriptions at Walgreens pharmacy retail locations in the State and received the medications at hospitals in the State.

20.6. **Defendant CVS Health Corporation** ("CVS") has its principal place of business at One CVS Drive, Woonsocket, Rhode Island and is incorporated under the

[38] http://investor.amerisourcebergen.com/static-files/fc6fce15-1eda-4ef3-94a8-72d64ffc0301
[39] http://investor.walgreensbootsalliance.com/secfiling.cfm?filingid=104207-13-104&cik=104207
[40] http://News.walgreens.com/fact-sheets/store-count-by-state.htm

laws of Delaware.[41] CVS conducts retail pharmacy operations at approximately 17 locations in Nebraska[42] with additional locations in or near Plaintiff's service areas in South Dakota and Iowa. CVS retail pharmacies sold and distributed opioid prescriptions to Nebraska residents including including persons for whom Plaintiff provides services. These persons filled opioid prescriptions at CVS's pharmacy retail locations, and received the medications at hospitals in Plaintiff's service areas including Nebraska.

Pharmaceutical Defendants

Purdue, Cephalon, Johnson, Janssen, Endo, and Actavis, Insys and Mallinckrodt are collectively referred to hereinafter as the "Pharmaceutical Defendants."

20.7. **The Purdue Companies.** All the Purdue companies named in this paragraph are sued and they are referred to collectively as "Purdue".[43] The company's different branches include **Defendant Purdue Pharma L.P., Defendant The Purdue Frederick Company**, **Defendant Purdue Pharmaceutical Products L.P.** and **Defendant Purdue Products L.P.**[44] **Purdue Pharma L.P.** is a limited partnership organized under the laws of Delaware. Purdue Pharma, Inc. is a New York corporation with its principal place of business at One Stamford Forum, 201 Tressor Blvd, Stamford, CT 06901, and **The Purdue Frederick Company** is a Delaware corporation with its principal place of business at One Stamford Forum, 201 Tressor Blvd, Stamford, CT 06901(collectively, "Purdue"). **Purdue Pharmaceutical Products L.P.** is a limited

41 https://www.sec.gov/Archives/edgar/data/64803/000006480315000008/cvs-20141231x10k.htm

42 https://www.cvs.com/store-locator/cvs-pharmacy-locations/Nebraska/Columbus

43 For general ownership descriptions, see *"The Secretive Family Making Billions From the Opioid Crisis". 16 October 2017. Retrieved 11 February 2018; and Keefe, Patrick Radden (2017-10-23). "The Family That Built an Empire of Pain". The New Yorker. ISSN 0028-792X. Retrieved 2018-01-19.*

44 For a description of Purdue Pharma, see http://www.purduepharma.com/contact/

partnership organized under the law of Delaware with a principal place of business at Wilson, North Carolina. **Purdue Products L.P**. is a limited partnership organized under the law of Delaware with places of business in Rhode Island and New Jersey. The company's manufacturing takes place at three different sites, Purdue Pharmaceuticals L.P. a plant located in Wilson North Carolina, The P.F. Laboratories Inc. in Totowa, New Jersey and Rhodes Technologies L.P. in Coventry Rhode Island. Purdue Pharma L.P. also has research labs in Cranbury, New Jersey. Oxycontin is currently distributed throughout the U.S., Canada and Mexico. Distribution takes place from the P.F. Laboratories Inc. in Totowa, New Jersey. Purdue manufactures, promotes, sells, and distributes opioids such as Oxycontin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the United States and Nebraska and the Ponca Tribe's service area. Oxycontin is Purdue's best-selling opioid product. Since 2009, Purdue's annual sales of Oxycontin are believed to have fluctuated between $2.5 billion and $3.0 billion, up four-fold from its 2006 sales of $800 million. Oxycontin constitutes approximately 30% of the entire market for analgesic drugs (painkillers). All the Purdue Companies work in combination with one another, coordinate efforts, share management ideas and meetings, and engage in strategic planning based on the circumstances of one another. They constitute an enterprise, and participate with the other Defendants to form a larger enterprise. The Purdue enterprise has international aspects including **Mundipharma**, a Purdue –affiliated and commonly owned worldwide network of pharmaceutical companies not constrained

by U.S. Court orders, engaged enterprise-wide, around the world in exploitation with opioids.[45]

20.8. **Defendant Cephalon, Inc**. ("Cephalon") is a Delaware corporation with its principal place of business at 41 Moore's Road, Frazer, Pennsylvania.[46] Cephalon manufactures, promotes, sells, and distributes opioids such as Actiq and Fentora in the United States and the Ponca Tribe's service areas and Nebraska. Actiq and Fentora have been approved by the FDA only for the "management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain." In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay $425 million.

20.9. **Defendant Teva Pharmaceutical Industries, Ltd.** ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel and with a headquarters location in the United States at 145 Brandywine Pkwy, West Chester PA 19380. **Defendant Teva Pharmaceuticals USA, Inc.** ("Teva USA") is a wholly-owned subsidiary of Teva Ltd. and is a Delaware corporation with its principal place of business in Pennsylvania. Teva USA acquired Cephalon in October 2011. Teva proclaims that it provides "global leadership driven by innovation and uncompromising quality."[47]

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[45] Keith Humphreys et al., *Opioids of the Masses*, Foreign Affairs Magazine (May/June 2018).
[46] https://www.sec.gov/Archives/edgar/data/873364/000104746911000780/a2201824z10-k.htm
[47] http://www.tevapharm.com/about/. Also see, http://www.tevapharm.com/featuredstories/?itemid=%7B7E74A827-65B8-4A6E-B087-5A2300DF52ED%7D

20.10. **Defendants Teva Ltd., Teva USA, and Cephalon**[48] collaborate to market and sell Cephalon products in the U.S. Teva Ltd. conducts all sales and marketing activities for Cephalon in the U.S. through Teva USA. Teva Ltd. and Teva USA publicize Actiq and Fentora as Teva products. Teva USA sells all former Cephalon branded products through its "specialty medicines" division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids marketed and sold in the Ponca Tribe service area, discloses that the Guide by Teva USA, directs physicians to contact Teva USA to report adverse events. Teva Ltd. directed Cephalon to disclose that it is a wholly-owned subsidiary of Teva Ltd. on prescription savings cards distributed in the Ponca Tribe service area, indicating Teva Ltd. would be responsible for covering certain co-pay costs. All of Cephalon's promotional websites, including those for Actiq and Fentora, prominently display Teva Ltd.'s logo. Teva Ltd.'s financial reports list Cephalon's and Teva USA's sales as its own. Through these related operations, Teva Ltd. operates in the Ponca Tribe's service areas through its subsidiaries Cephalon and Teva USA. The United States is the largest of Teva Ltd.'s global markets, representing 53% of its global revenue in 2015. Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. (Teva Ltd., Teva USA, and Cephalon, Inc. are hereinafter collectively referred to as "Cephalon.")

20.11. All the Teva Companies and Cephalon work in combination with one another, coordinate efforts, share management ideas and meetings, and engage in

[48] History and relationships detailed in part at SEC filings at https://www.sec.gov/Archives/edgar/data/873364/000104746911000780/a2201824z10-k.htm

strategic planning based on the circumstances of one another. They constitute an enterprise, and participate with the other Defendants to form a larger enterprise.

20.12. **The Janssen Companies and Johnson & Johnson. Defendant Janssen Pharmaceuticals, Inc.**[49] is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of **Johnson & Johnson (J&J),** a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.[50] **Defendant Ortho-McNeil Janssen Pharmaceuticals, Inc.,** now known as **Janssen Pharmaceuticals, Inc**., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Janssen Pharmaceutica Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the controlling shareholder of Janssen Pharmaceuticals' stock, and corresponds with the FDA regarding Janssen's products. J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. (Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and J&J hereinafter are collectively referred to as "Janssen."). Janssen manufactures, promotes, sells, and distributes drugs in the United States and the Ponca Tribe service area, including the opioid Duragesic. Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

[49] http://www.janssen.com/us/
[50] https://www.sec.gov/Archives/edgar/data/200406/000020040616000071/form10-k20160103.htm

20.13. **Janssen Pharmaceuticals, Inc.** maintains a physical presence in Nebraska at 11128 John Galt Blvd #125, Omaha NE 681347.

All the Janssen Companies work in combination with one another, coordinate efforts, share management ideas and meetings, and engage in strategic planning based on the circumstances of one another They constitute an enterprise, and participate with the other Defendants to form a larger enterprise..

20.14. **Defendant Endo Health Solutions Inc.** is a Delaware corporation with its principal place of business in Malvern, Pennsylvania [51] **Defendant Endo Pharmaceuticals Inc.** is a wholly-owned subsidiary of Endo **Health Solutions Inc.** which is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.[52] (Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. hereinafter are collectively referred to as "Endo.") Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone in the United States, the Ponca Tribe's service areas and Nebraska. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the United States and the Ponca Tribe's service areas, by itself and through subsidiary, Qualitest Pharmaceuticals, Inc.

[51] http://www.endo.com/our-companies/endo-pharmaceuticals
[52] SEC for 10k; https://www.sec.gov/Archives/edgar/data/1100962/000119312511288958/d234466dex21.htm

For a time the Endo companies manufactured their opioid drugs including Percocet and Percodan (an aspirin, opioid combination) under contract with Novartis at its Lincoln, Nebraska plant. Plaintiff does not know when this arrangement terminated.[53]

All the Endo Companies work in combination with one another, coordinate efforts, share management ideas and meetings, and engage in strategic planning based on the circumstances of one another. Accordingly, they constitute, themselves, an enterprise, and participate with the other Defendants to form a larger enterprise.

20.15. **Defendant Allergan PLC** is a public limited company incorporated in Ireland with its principal place of business in Dublin, D14 E400, Ireland. Actavis PLC acquired Allergan PLC in March 2015, and the combined company changed its name to Allergan PLC in January 2013. Before that, Watson Pharmaceuticals, Inc. acquired Actavis, Inc. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013, later to Actavis PLC in October 2013. Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan PLC (f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.).

Actavis Pharma, Inc. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as Watson Pharma, Inc. Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these Defendants is owned by Allergan

[53] Am Ass'n of Family Practitioners, AAFP News, *Novartis Closes Nebraska Production Facility After Reports of Drug Mix-Ups.* (AAFP News 1.11.2012). https://www.aafp.org/News/health-of-the-public/20120111novartisrecall.html

PLC, which uses them to market and sell its drugs in the United States. Upon information and belief, Allergan PLC exercises control over and derives financial benefit from the marketing, sales, and profits of Allergan/Actavis products. (Allergan PLC, Actavis PLC, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. hereinafter are referred to collectively as "Actavis.") Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the United States, Nebraska and the Ponca Tribe service area. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

All the Allergan Companies work in combination with one another, coordinate efforts, share management ideas and meetings, and engage in strategic planning based on the circumstances of one another. They constitute an enterprise, and participate with the other Defendants to form a larger enterprise.

20.16. **Defendant Insys Therapeutics, Inc.** ("Insys") is a Delaware corporation with its principal place of business in Chandler, Arizona. Insys commenced to manufacture the opioid medication known as Subsys in 2012.

20.17. **Defendant Mallinckrodt plc** is a public limited company organized under the law of Ireland with its headquarters at Staines-Upon-Thames, Surrey, United Kingdom. **Defendant Mallinckrodt Pharmaceuticals** is a Delaware corporation with its principal place of business at Hazelwood, Missouri.

The Background Facts
Opioids

21. "Opioid" is a term that means what "narcotic" once meant. "Opioid" is a more current term for opium, opium derivatives and their semi-synthetic substitutes as well as illicit heroin and synthetic opioids.[54] These are synthetics are what Defendants manufacture and distribute and are the substances at the core of this case. Every opioid manufactured and distributed by Defendants and identified in this Complaint directly, or by association, was and is a "drug, medicine or medicinal substance" as defined by *Neb Rev Stat* § 71-2467 and the *Federal Controlled Substances Act*, 21 U.S.C. § Ch 13.

22. The United States Food and Drug Administration's website describes this class of drugs as follows:

> "Prescription opioids are powerful pain-reducing medications that include prescription oxycodone, hydrocodone, and morphine, among others, and have both benefits as well as potentially serious risks. These medications can help manage pain when prescribed for the right condition and when used properly. But when misused or abused, they can cause serious harm, including addiction, overdose, and death."[55]

23. Prescription opioids with the highest potential for addiction are categorized under Schedule II of the *Federal Controlled Substances Act*.[56] They include non-synthetic derivatives of the opium poppy (such as codeine and morphine, also called

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[54] US Drug Enforcement Admin "Drug Fact Sheet" accessible at *https://www.dea.gov/druginfo/drug_data_sheets/Narcotics.pdf*

[55] *https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm337066.htm*

[56] 21 USC Ch 13. Schedules I. – V. found at 21 USC § 812. Regulatory identification of specific scheduled drugs found at 21 CFR Pt 1308.

"opiates"), partially synthetic derivatives (such as hydrocodone and oxycodone), or fully synthetic derivatives (such as fentanyl and methadone).

24. Before the epidemic of Defendants' prescription opioids, the generally accepted standard of medical practice was that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. Medical doctors generally did not prescribe opioids for chronic pain. Recent studies confirm that these earlier perceptions of opioids for pain control were correct. These findings were and are collected in a 2017 publication by the National Academies of Sciences.[57]

25. Defendants, however, campaigned in a concerted effort, and expended large sums of money, and executed joint, mutual or compatible in fact marketing plans to persuade health care providers that the standard of professional care recognized opioids as superior for pain control and required that they be prescribed. They abused publications and other data, and misread represented facts to do so. This may have all begun with a 1980 brief letter published in the *New England Journal of Medicine.* This brief letter reported that less than 1% of patients at Boston University Medical Center

[57] National Academies of Sciences et al., *Pain Management and the Opioid Epidemic, Balancing Societal & Individual Benefits & Risks of Prescription Opioid Use* (Nat'l Academies Press July 12, 2017).

who received narcotics while hospitalized became addicted.[58] The letter was abused by the industry, including Defendants. The industry quickly seized upon this letter and developed and propagated opioid medications at a rapid pace.[59] In the years following publication of the 1980 Letter to the Editor and the Portenoy Publication, the Manufacturing Defendants introduced powerful prescription opioids into the market. Purdue introduced MS Contin in 1987 and Oxycontin in 1995, Janssen introduced Duragesic in 1990 and Cephalon's Actiq was first approved by the FDA in 1998. More recently, Endo's Opana and Opana ER were approved by[60] the FDA in 2006, as was Janssen's Nucynta in 2008 and Nucynta ER in 2011, Cephalon's Fentora in 2006 and Insys' Subsys in 2012.

26. The Defendants' prescription opioids, including both branded and generic products, are highly addictive. Once introduced into the body, patients quickly become dependent upon them.[61] Dependency is in part caused by cycle drug usage. Opioid use, relief , more opioids, creates an addictive cycle of dependency including states of cycling dysphoria and euphoria and addiction and dependence.

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58 In 1980, the *New England Journal of Medicine* published a 100-word letter to the editor by Jane Porter ("Porter") and Dr. Herschel Jick ("Jick"). It reported that fewer than 1% of patients at Boston University Medical Center who received narcotics during hospital stays became addicted. Jane Porter & Hershel Jick, *Addiction rate in patients treated with narcotics*, 302(2) New Eng. J. Med. 123 (Jan. 10, 1980).

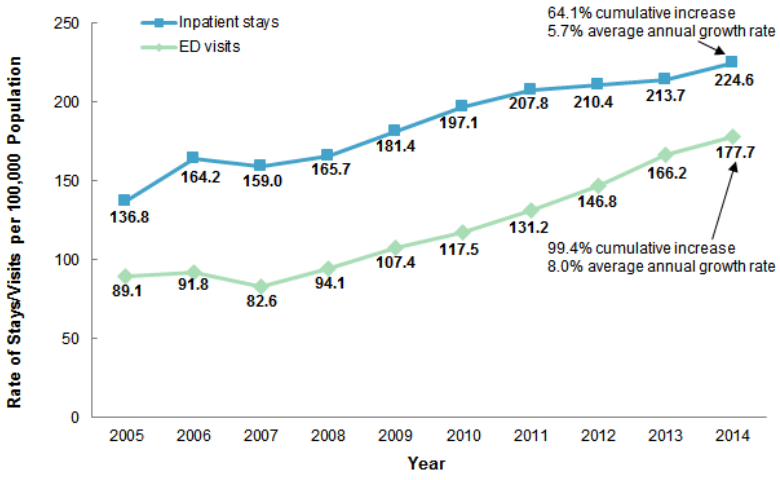
59 The letter and results reported were far too simplistic to support the conclusion for which it was often misused by the Defendants. This is chronicled at Harrison Jacobs, *This one-paragraph letter may have launched the opioid epidemic*, Bus. Insider (May 26, 2016), http://www.businessinsider.com/porter-andjick- letter-launched-the-opioid-epidemic-2016-5 ("Jacobs, *One-paragraph letter*"). A 2009 article in the *American Journal of Public Health*, revealed that 1980 Letter to the Editor "shed[] some light on the risk of addiction for acute pain, [but did] not help establish the risk of iatrogenic addiction when opioids are used daily for a prolonged time in treating chronic pain." The 2009 article continued, "[Indeed, t]here are a number of studies . . . that demonstrate that in the treatment of chronic non-cancer-related pain with opioids, there is a high incidence of prescription drug abuse." Art Van Zee, *The Promotion and Marketing of Oxycontin: Commercial Triumph, Public Health Tragedy*, 99(2) Am. J. Pub. Health 221-27 (Feb. 2009).

60 Jacobs, *One-paragraph letter*, *supra* n.50;

61 Andrew Kolodny, *Opioids for Chronic Pain: Addiction is NOT Rare*, YouTube (Oct. 30, 2011),https://www.youtube.com/ watch?v=DgyuBWN9D4w&feature=youtu.be).

27. Defendants persistently caused and permitted massive quantities of opioids to be diverted from legitimate destinations to highly suspect, but unreported, and overtly illicit recipients in the Ponca Tribe service areas, and across the United States. From these recipients they pass on the gray and black markets to nonprescription users who turn many of them into street drugs, sell them to addicts and persons who become addicts, and make them available for persons who are unregulated by competent medical care providers. Defendants ignored their lawful duties, failed to perform them, and caused the opioid crisis and the damages Plaintiff seeks.

28. Plaintiff provides and supports care to emergency and first responder patients. Opioid victims require greater emergency services as shown here:



Neonatal Abstinence Syndrome Patients

29. Some opioid victims who are members of the Ponca Tribe are babies born with Neonatal Abstinence Syndrome ("NAS"), a condition suffered by babies of mothers addicted to opioids. These patients require extensive care and will demand public health, juvenile, law enforcement and correctional services at Plaintiff's facilities because they

are likely to experience dramatically increased mental health, developmental impairment, and physical health limitations for as long as they live. These patients do now demand excess services and require excess costs to be incurred by the Ponca Tribe.

30. The incidence of NAS has been increasing in the United States and in Nebraska. The Substance Abuse Mental Health Services Administration ("SAMHSA") reported that 1.1% of pregnant women abused opioids (0.9% used opioid pain relievers and 0.2% used heroin) in 2011.[62] This is also true in Nebraska and the Ponca Tribe service area, where the NAS incidence rate is now above the national average. There has been a dramatic recent rise in the number of fetuses and infants that have been exposed to opioids. Women are also victims of opioids and patients whose care requirements drive up unreimbursed costs for Plaintiff.[63]

31. Heroin and other opioid misuse during pregnancy are also associated with increased risks and incidence of placental abruption, preterm labor, maternal obstetric complications, maternal mortality, and fetal death.[64] This causes increased demands for services, and costs to the Ponca Tribe. The consequences of addiction also drive up housing costs because of increased vandalism, destruction and damages, including events damaging tribal property and injuring Ponca tribal members, and cause direct exacerbation of tribal costs and damages.

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[62] The *Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and Their Infants* is available in the online SAMHSA Store at https://store.samhsa.gov/product/SMA18-5054

[63] Final Report: Opioid Use, Misuse and Overdose in Women, USDHHS, Office of Women's Health, The *Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and Their Infants* is available in the online SAMHSA Store at https://store.samhsa.gov/product/SMA18-5054

[64] Karen McQueen et al., *Neonatal Abstinence Syndrome,* N Engl J Med 375:2468-2479 (Dec 22, 2016), accessible at http://www.nejm.org/doi/full/10.1056/NEJMra1600879

32. NAS babies' mothers purchase and consume prescription opioids from one or both Pharmacy Defendants or obtain them from other sources. These patients will, in turn require increased costs for the services provided by the Ponca Tribe.

Victims In the Court System

33. Some opioid victims in the Ponca Tribe service areas and among its members are charged with offenses, convicted of crimes, or suffer loss of liberty due to actions, alleged actions and mental health circumstances. The number has grown dramatically and continues to grow.

34. Some Ponca Tribe members become incarcerated in the criminal justice systems of the federal or state governments, or county governments, and require services from the Tribe upon release. This exacerbates costs. Sixty-five percent of all such individuals meet criteria for a substance abuse disorder.[65] Use of opioids—which include prescription pain relievers, heroin, and synthetic opioids such as fentanyl—is linked with a higher rate of recidivism.[66] It is generally accepted that certain medications including buprenorphine, methadone, and extended release naltrexone, are first-line treatments for opioid addiction.[67] These medications decrease opioid use, opioid-related overdose deaths, criminal activity, and infectious disease transmission while increasing social

[65] Behind Bars II: Substance Abuse and America's Prison Population (2010) The National Center on Addiction & Substance Abuse, https://www.centeronaddiction.org/addiction-research/reports/behind-bars-ii-substance-abuse-and-america%E2%80%99s-prison-population

[66] Nat'l Inst on Drug Abuse, *Treating Opioid Addiction in Criminal Justice Settings*, https://www.drugabuse.gov/publications/treating-opioid-addiction-in-criminal-justice-settings/treating-opioid-addiction-in-criminal-justice-settings

[67] Mattick, RP, *Buprenorphinie Maintenance v. Placebo or Methadone Maintenance for Opioid Dependence*, Cochrance Database Syst Rev 2015, PMID: 24500948

functioning and retention in treatment.[68] It is known that medications should be combined with behavioral counseling for a "whole patient" approach, known as Medication Assisted Treatment (MAT). But, medication for detoxification alone is not effective for promoting long-term abstinence. Inmates treated with methadone or buprenorphine prior to release are more likely to engage in post-release treatment, and to stay in treatment longer.[69] A National Institute on Drug Abuse-funded study found treatment with extended-release naltrexone reduced relapse rates among criminal justice-involved adults with a history of opioid dependence.[70] Over 97% of those receiving methadone continued treatment after release.[71]

Acute Care, and Mental Health Care, Patients

35. Some of the victims of opioids are persons who require psychiatric or psychological care and support. These persons' needs exacerbate Plaintiff's operating costs and losses by demanding and consuming more services, but cannot pay for them. Opioid dependent patient mental health needs must be met with specialized, costly services which patients commonly cannot pay for. Those services are provided in compliance with Federal Guidelines for Opioid Treatment Programs.[72] These Guidelines are themselves, controversial; this controversy produces uncertainty among practitioners

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[68] Lee, JD, *Extended – Release Naltrexone to Prevent Opioid Relapse In Criminal Justice Offenders*, 374 New Eng Journal Med 1232 (2016).

[69] Zaller, N, *Buprenorphine During Incarceration & Retention in Treatment Upon Release*, 45 Journal of Substance Abuse Treatment 222 (2013). Lee, JD, *Extended – Release Naltrexone to Prevent Opioid Relapse In Criminal Justice Offenders*, 374 New Eng Journal Med 1232 (2016).

[70] Id.

[71] Westerberg, VS, *Community-Based Methadone Maintenance in a Large Detention Center Associated with Decreases in Inmate Recidivism*, 70 J. Substance Abuse & Treatment 1 (2016).

[72] Program requirements described at https://store.samhsa.gov/shin/content/PEP15-FEDGUIDEOTP/PEP15-FEDGUIDEOTP.pdf

serving patients with genuine, chronic and unremitting pain, and who require additional consultations, decision time, and costs.

The Scope of the Opioid Problem

36. Plaintiff's losses due to demands for services to opioid victims are part of an opioid epidemic sweeping through the United States, including Indian Country that causes infants and older patients great suffering and continuing developmental issues. In 2016, then President of the United States Barack Obama proclaimed:

> Opioid use disorder, or addiction to prescription opioids or heroin, is a disease that touches too many of our communities -- big and small, urban and rural -- and devastates families, all while straining the capacity of law enforcement and the health care system. States and localities across our country, in collaboration with Federal and national partners, are working together to address this issue through innovative partnerships between public safety and public health professionals.[73]

37. On October 26, 2017, the current President of the United States proclaimed similar matters with updated statistics. On March 14, 2018, a member of the National Indian Health Board reinforced testimony given by the Chief Executive Officer of NIHB before a House Energy & Commerce Committee hearing entitled *Combating the Opioid Crisis: Prevention & Public Health Solutions*.[74] Data included these statistics:

37.1. The rate of drug overdose deaths in the American Indian and Alaska Native populations is double the rate of the general population of the United States.

[73] https://obamawhitehouse.archives.gov/the-press-office/2016/09/16/presidential-proclamation-prescription-opioid-and-heroin-epidemic

[74] http://campaign.r20.constantcontact.com/render?m=1110714960954&ca=6234cd3d-11fd-4ee6-99d3-cad090eb37be

37.2. Deaths from prescription opioid overdoses increased four-fold from 1999 to 2013 among AI/ANs.

37.3. AI/ANs have the highest drug overdose death rate by race at the present time and have had every year since 2015. During the same time they had the highest percentage increase in drug overdose deaths, an increase of 519%.[75]

38. In 2016, 4.1% or more than 1 in 25 American Indian and Alaska Natives age 12 and older reported opioid misuse during the prior year. This is substantially identical to the rate for non-natives. But, incidence among Native American communities is widely believed to be underreported.[76] The opioid overdose rate reported by the U.S. Center for Disease Control (CDC) for Native Americans is 8.4/100,000. In 2014, the number of babies born drug-dependent had increased by 500 percent in the United States, and by a larger rate in Indian Country. Since 2000, nearly one-third of allchildren placed in foster care go there due to parental drug abuse.[77]

39. In 2016, deaths due to opioids increased 24% over the prior year in Nebraska.[78] The increased even more in Indian Country. The death rate has continued to climb since year end 2016. CDC is working with Plaintiff and hospitals in 45 States and Washington DC to gather and report Opioid related medical care needs.[79] Emergency

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[75] Mack KA, Jones CM, Ballesteros MF. Illicit Drug Use, Illicit Drug Use Disorders, and Drug Overdose Deaths in Metropolitan and Nonmetropolitan Areas - United States. MMWR Surveill Summ 2017;66(No. SS-19):1-12. DOI: http://dx.doi.org/10.15585/mmwr.ss6619a1

[76] https://www.indian.senate.gov/news/press-release/hoeven-holds-hearing-combating-opioid-abuse-epidemic-indian-country (March 2018)(US Sen John Hoeven, ND).

[77] *Id*.

[78] Reported at https://www.cdc.gov/drugoverdose/data/statedeaths.html

[79] https://www.cdc.gov/drugoverdose/states/index.html

department and acute care demands have also increased. The U.S. Department of Health and Human Services has called the problem a "public health emergency".[80] These circumstances are also present in the Ponca Tribe service area. While the mortality rate is not yet as high in Nebraska as some other parts of the United States, it is escalating and costs associated with addictions, and co-addictions including opioids have dramatically increased the costs of government operations for the Ponca Tribe.

Plaintiff's Resources Are Not Adequate

40. The budgetary, human and physical resources of the Ponca Tribe are inadequate to deal with the rapidly growing crisis.

Defendants' Wrongful Conduct
(Including Criminal Convictions and Civil Penalties)

41. The allegations above describing actions and omissions of the Defendants are renewed here.

42. The opioid epidemic, including the NAS epidemic and their consequences could have been, and should have been, prevented by the Defendants who control the U.S. drug distribution industry and the Defendants who manufacture the prescription opioids. The Defendants have profited greatly by allowing Plaintiff's service area to become flooded with patients requiring service for conditions caused by opioids.

43. The drug distribution industry, including Pharmaceutical, Distributor and the Pharmacy Defendants, have a legal duty to serve as a "check" in the opioid delivery system by securing and monitoring opioids throughout the stream of commerce,

[80] Statement of Acting DHHS Secretary Eric Hargan. https://www.hhs.gov/about/News/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html

protecting them from diversion and misuse, and refusing to fulfill suspicious or unusual orders by downstream pharmacies, doctors, clinics, or patients. Defendants each breached this duty and failed in their obligation, instead consciously ignoring known or knowable problems and data in their supply chains. McKesson and the Distributor Defendants breached this statutory obligation by ignoring known or knowable problems and data and their supply chains. McKesson's action including wrongdoing at its La Vista, Nebraska distribution center resulting in a $150 million civil penalty levied in early 2017 to settle violations of the *Federal Controlled Substances Act.*[81]This is discussed more, below.

44. The Defendants intentionally and negligently created conditions in which vast amounts of opioids have flowed freely from drug manufacturers to innocent patients who became addicted, to opioid abusers, and even to illicit drug dealers - with distributors regularly fulfilling suspicious orders from pharmacies and clinics, who were economically incentivized to ignore "red flags" at the point of sale and before dispensing the pills.[82] These red flags are:

1. Taking medication but not as prescribed.
2. Taking opioid meds for reasons other than pain.
3. Running out of your opioid medication early.
4. Preoccupation with your opioid medication.
5. Changing the way you take opioids to "boost" effect.
6. Your family is worried about you.[83]

[81] U.S. DOJ Press Release, *McKesson Agrees to Paying Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs* (January 17, 2017) https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders

[82] The six Red Flags of opioid addiction are well known. https://health.clevelandclinic.org/the-6-red-flags-of-opioid-addiction/

[83] *Id.*

45. Defendants' wrongful conduct allowed millions of opioid pills to be diverted from legitimate channels of distribution into the illicit black market in quantities that have fueled the opioid epidemic in Nebraska. This is called "opioid diversion." Defendants created an environment in which opioid diversion is rampant. Unknowing patients and unauthorized opioid users have ready access to illicit diverted opioids.

46. For years, Defendants and their agents had the ability to substantially reduce the consequences of opioid diversion, including the dramatic increase in the number of infants born with NAS. All the Defendants in this action share responsibility for perpetuating the epidemic and the exponential increase in the number of infants afflicted with NAS and the number of other patients adversely affected.

Pharmacy Defendants

47. Pharmacies, including the Pharmacy Defendants Walgreen's and CVS, have a role to play in the oversight of prescriptions for controlled substances, and opioid analgesics in particular. Under the *Controlled Substances Act*, pharmacists must evaluate patients to ensure the appropriateness of any controlled-substance prescription. In addition, state boards of pharmacy regulate the distribution of opioid analgesics and other controlled substances through the discretion of pharmacists.

48. Chain pharmacies have the advantage of aggregated information on all prescriptions filled at the chain.[84] This permits identification of prescription abusers, doctor shoppers, and roving patients. As early as 2013, the DEA identified chain pharmacies as part of the problem, demanding development of new programs to reduce

[84] Betses, RPh et al, *Abusive Prescribing of Controlled Substances – A Pharmacy View*, 369 New Eng J Med 989 (Sept 12, 2013)

inappropriate opioid use.[85] In 2012 the DEA served an Administrative Inspection Warrant on Walgreens in an investigation of the legitimacy of medical prescriptions filled by the company and an investigation of Walgreens professional practices. In September 2012, a Walgreens Distribution Center was served by the DEA with an Immediate Suspension of Registration and in November 2012 Orders to Show Cause were served on three Florida Walgreen pharmacies.[86]

49. Defendant CVS agreed to pay an $8 million fine to the United States to resolve allegations that its Maryland pharmacies violated the *Controlled Substances Act*[87] by dispensing substances pursuant to prescriptions that were not issued for legitimate medical purposes.[88] In its press statement, the DEA Special Agent In Charge said "This abuse has directly resulted in the escalation of heroin addiction and related overdose. Today's settlement sends a clear message to all pharmacies that it is essential to dispense controlled substance is in compliance with DEA's record keeping requirements. At the same time the United States Attorney for the District of Maryland, Rod J Rosenstein said "pharmacies that dispense controlled substances have a duty to ensure that prescriptions they feel were issued for legitimate medical purposes." Rosenstein continued, "Doctors and pharmacists are the gatekeepers of the effort to prevent the abuse and diversion of pharmaceutical drugs for non-medical purposes."[89]

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[85] Drug Enforcement Administration. DEA serves another Walgreens pharmacy an order to show cause. February 6, 2013 (http://www.justice.gov/dea/divisions/mia/2013/mia020613.shtml).
[86] *Id.*
[87] *Controlled Substances Act*, 21 USC § 801 et seq.
[88] Drug Enforcement Administration. DEA Press Release, February 12, 2016, Baltimore MD. https://www.dea.gov/divisions/wdo/2016/wdo021216.shtml
[89] *Id.*

50. In the 2016 settlement with the DEA, CVS acknowledged that between 2008 and 2012 CVS pharmacy stores dispense controlled substances, including oxycodone, fentanyl and hydrocodone, in a manner not fully consistent with their compliance obligations under the *Controlled Substances Act* and related regulations. This included failing to comply with the duty of pharmacists to ensure that controlled substance prescriptions are issued for legitimate medical purposes.[90] In 2017 CVS agreed with DEA to pay $5 million for record keeping failures for Schedule II and other drugs including opioids. In announcing the fine, the DEA Special Agent in Charge in San Francisco said:

> The nation is in the midst of an opioid crisis and all entities that distribute controlled substances must hold the frontline. Regulatory compliance and accurate recordkeeping are indispensable in a pharmacy's ability to prevent prescription drug diversion.[91]

51. The Pharmacy Defendants are reasonably believed to have committed similar acts and omissions here.

52. The Defendants engaged in both criminal conduct and conduct producing serious civil penalties and sanctions as punishments for intentional wrongful conduct. Acts of the Pharmacy Defendants are detailed in the previous section of this Complaint.

53. The criminal and civil acts and omissions, and the tortious conduct of the Defendants in all categories acted in concert to form, create, and carry out inserted action, and a course of conduct and usage constituting an enterprise in fact used to implement a

[90] *Id.*
[91] DEA Press Release, CVS Pharmacy Inc. Pays $5m…" (July 11, 2017). https://www.dea.gov/divisions/sf/2017/sf071117.shtml

multi-fronted conspiracy. The conspiracy may have had a centralized command and initiation process, or it may have operated de facto in a follow the leader methodology. In either event, it included the criminal and civil actions described above and below and the tortious acts and omissions detailed in this Complaint. Both individually and collectively, the acts and omissions of the Defendants caused the damages and losses for which Plaintiff seeks judgment.

54. The Defendants named acted in concert with other conspirators who are not named or whose identities are not yet known.

Defendant Purdue Companies

55. The Purdue Companies, privately held by a single family, sell its manufactured and marketed opioid drug products in the state of Nebraska and to Plaintiff, and worldwide. Its array of medications include:

Drug Name	Description	Schedule
Oxycontin (Oxycodone hydrochloride extended release)	Opioid agonist indicated for pain severe enough to require daily around-the-clock long term opioid treatment; not indicated as an as-needed analgesic.	II
MS Contin (Morphine sulfate extended release)	Opioid agonist; controlled release tablet form morphine sulfate indicated for management of severe pain. Not intended for use as a PRN analgesic. First formulation of an opioid pain medication that allowed dosing very twelve hours.	II

Dilaudid (Hydromophone, hydrochloride, opioid analgesic)	Injectable & oral formulation. Eight times more potent than morphine.	II
Dilaudid HP (Hydromophone, hydrochloride, opioid analgesic)	Injectable & oral high potency and highly concentrated formulation indicated for relief of moderate-to-severe pain in opioid-tolerate patients.	II
Hysingla ER (Hydrocodone bitrate)	Brand name extended release form of hydrocodone bitrate that is indicated for the management of severe pain.	II
Targiniq ER (Oxycodone, hydrochloride and naloxone hydrochloride	Brand name extended release opioid analgesic made of a combination of oxycodone, hydrochloride, and naloxone hydrochloride. Approved in 2013.	II

55.1. It is believed that more than 500,000 prescriptions for Oxycontin alone were written in the State of Nebraska for the years 2013-2016 inclusive. In 2015, 1.4 million opioid prescriptions were written in Nebraska. Persons served by purchased and used the opioid medications identified above, and did so relying on Purdue's statements concerning its products. More than one third of these were written in Douglas County which is one of the Ponca Tribe's service areas.

55.2. Purdue falsely marketed its extended relief drugs as safer as and more effective than other regular release products. This effort commenced with Oxycontin when Purdue declared that one dose of Oxycontin would relieve pain for twelve hours, more than twice as long as generic mediations.[92] Repeated assurances were made that opioids were effective and non-

[92] Harriet Ryan, et al., *You want a description of hell? Oxycontin's Twelve-Hour Problem*. LA Times (May 5, 2016)

addictive. With these assurances, Oxycontin became the best-selling pain killer in the United States.[93]

55.3. Purdue's nationwide marketing claims were deceptive. Purdue's own studies displayed a high level of addiction after its use, notwithstanding its contrary assertions in its promotions, descriptions, and accounts of its product. Essentially, the drug would wear off hours before a twelve-hour dosage was to end, producing an intense desire and craving for an additional amount of the drug. Some experts referred to Oxycontin as an addiction producing machine.[94] Purdue persisted in marketing Oxycontin despite its internal awareness and acknowledgements that it would face stiff resistance from doctors concerned that a high-powered narcotic like Oxycontin would be abused by patients or cause addiction. Purdue, however, promised that its long-acting extended release formulation would make it less prone to such problems.[95]

55.4. Purdue developed a sales culture that promoted sales at any cost. Aggressive quotas were used for Oxycontin sales and dosages as well as Hysingla products. Performance plans were jeopardized or terminated when representatives failed to meet sales quotas, but when they did, they

[93] Press release, Purdue Pharma LP, New Hope for Millions of Americans Suffering from Persistent Pain: Long-acting Oxycontin Tablets Now Available to Relieve Pain (May 31, 1996).

[94] Kathleen Frydel, Purdue Pharma: *Corporate Fraud with a Body Count*, Alternet (May 18, 2016), https:www.alternate.org/drugs/purdue-pharma-corporate-fraud-body-count.

[95] Barry Meyer, *In Guilty Plea, Oxycontin Maker to Pay Six Million Dollars*, New York Times (May 10, 2007).

were rewarded with extravagant bonuses and prizes, including travel to desirable destinations.

55.5. In addition, Purdue promoted Oxycontin as safe and non-addictive. It did so by representing its extended release formulation as creating a lower risk of addition or abuse. It promoted use of prescription opioids in non-cancer patients who make up more than 80% of the total opioid market.[96]

55.6. Purdue supplied its sales representatives with coupons redeemable for seven to thirty day free supplies of Oxycontin, a Schedule II narcotic that cannot be prescribed for more than a month at a time, with the promise that it was a safe opioid. Purdue trained its sales representatives to carry the message that the risk of addiction was less than 1%, and, in addition, to minimize the risks of addiction when opioids were used to treat chronic non-cancer related pain. This continued until as late as 2015.[97]

55.7. Purdue tracked physician prescribing practices, but it did not report suspicious practices. Instead, it used the data to identify physicians who prescribed some opioids and might be persuaded to prescribe more. It could have identified physicians writing large prescriptions or prescriptions for high dose 80 mg pills, as these are known signs of diversion and drug dealing, but it did not do so.

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[96] Charles Ornstein, et al., *American Pain Foundation Shuts Downs as Senators Launch Investigation of Prescription Narcotics*, Propublica (May 8, 2012, 8:57 p.m.)

[97] Van Zee, *The Promotion and Marketing of Oxycontin: Commercial Triumph, Public Health Tragedy*, 99(2) Am J Pub Health, 221-227 (Feb 2009), https://www.ncbi.nlm.nih.gov/pmc/articles/pmc2622774/.

55.8. Purdue knew of suspicious doctors and pharmacies from prescribing records and its own surveillance. It maintained a confidential roster of suspected reckless prescribers and had a list of more than 1,800 doctors on the list which it called "Region Zero". This term was in use by or about 2013. But, Purdue reported only a small percentage—believed to be smaller to 10%—to authorities.

55.9. Purdue is believed to have paid FSMB more than $100,000 to print and distribute guidelines on the use of opioids to treat chronic pain to 700,000 practicing doctors, including members of the Nebraska licensing and oversight boards and regulators. In 2016 Purdue announced a "broad new partnership" with the Nebraska Medical Center "aimed at expanded "research and educational exchange in the neurosciences related to pain…"[98] Purdue used the event to continue to cover over its violations of the law and fraudulent, illegal sales of opioids in Nebraska and elsewhere.[99]

55.10. Purdue produced and distributed videos, including one in 2011 entitled "Optimizing Opioid Therapy", setting forth what it described as a "guideline for chronic opioid therapy" and discussing opioid rotation, i.e., switching from one to another. It described the consequence as a "balance of therapeutic good and adverse events over the course of years" and suggests that opioids could be used to treat sleep apnea as well as other

[98] http://News.purduepharma.com/press-release/unmc-purdue-pharma-enter-partnership-advance-new-drug-development

[99] One Nebraska physician, practicing at UNMC wrote 8,464 opioid prescriptions in 2015 alone… an average of just under 34 per day. https://projects.propublica.org/checkup/providers/1619925385

things.[100] Purdue also used and abused marketing agencies and front groups as alleged elsewhere in this Complaint. Its payments to NPF alone were hundreds of thousands of dollars.

55.11. In May 2007, Purdue and three (3) of its executives[101] pled guilty to federal criminal charges of misbranding Oxycontin in an attempt to mislead doctors about the risk of addiction. Purdue acknowledged this purpose. Purdue was ordered to pay $634,515,475 in fines and fees.[102] Its plea admitted that its promotion of Oxycontin was misleading and inaccurate and mispresented the risks of addiction. It admitted its statements were unsupported by science. In addition, the company's President pled guilty to misbranding and agreed to pay a $19 million fine, its top lawyer pled guilty and agreed to pay an $8 million fine, and its former medical director agreed to plead guilty and pay a $7.5 million fine.

55.12. The United States Attorney for the Western District of Virginia issued a press release describing Oxycontin's improprieties in detail.[103] In his characterization of Purdue's criminal activity he identified:

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100 Perry A. Fine, *Safe & Effective Opioid Rotation,* YouTube (November 8, 2012), https://www.utube.com/watch?v=g3II9yqgXI.

101 The three executives of Purdue who pled guilty to felonies are: Chief Executive Officer Michael Friedman, General Counsel Howard Udell, and former Chief Medical Officer Paul Goldenhiem. They were "responsible corporate officers" under 21 USC §§ 331(a), 333(a)(1), and 352(a).

102 Press release US Attorney, Western District of Virginia, Statement of US Attorney John Brownlee on Guilty Plea of Purdue Fredrick Company & Its Executives for Illegally Misbranding Oxycontin (May 10, 2007), https://assets.documentcloud.org/documents/279028/purdue-guilty-plea.pdf.

103 Id.

(1) Training sales representatives to falsely inform healthcare providers that it was more difficult to extract Oxycodone from an Oxycontin tablet for intravenous use;

(2) Falsely instructing sales representatives to inform healthcare providers that Oxycontin could create fewer chances for addiction.

(3) Sponsored training that falsely taught Purdue sales supervisors that Oxycontin had fewer "peak & draught" blood level effects than immediate release opioids resulting in less euphoria and less potential for abuse than short-acting opioids.

(4) False statements to healthcare providers that patients could stop therapy abruptly without experiencing withdrawal symptoms and those patients who took Oxycontin would not develop tolerance for it.

(5) False statements to healthcare providers that Oxycontin did not cause a "buzz" or euphoria and had less addiction potential and less abuse potential, and was less likely to be diverted than immediate release drugs. They actually said it could be used to "weed out" addicts and drug seekers.[104]

55.13. Purdue pled guilty specifically to illegally misbranding Oxycontin in an effort to mislead and defraud physicians, and its executives pled guilty to misdemeanor charges of misbranding Oxycontin and for introducing

[104] *Id.*

misbranded drugs into interstate commerce in violation of 21 *USC* §§ 331(a), 333(a)(1)-(2), and 352(a).

55.14. Even after being fined and prosecuted, Purdue continued to pay doctors on speakers' bureaus to promote liberal prescribing of Oxycontin for chronic pain and to fund front organizations to disseminate messages that opioids were effective and non-addictive.

55.15. Purdue is estimated to have earned as much as $31 billion from Oxycontin.[105]

55.16. Purdue was required by the *Comprehensive Drug Abuse Prevention & Control Act* of 1970, 21 *USC* § 801 *et seq*., and regulations thereunder, to design and operate a system to disclose to Purdue, as registrant, suspicious orders or diversions of controlled substances, and to promptly notify the US Drug Enforcement Administration ("DEA") of any such suspicions. By definition "suspicious orders" include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency". 21 *CRF* § 1301.74(b).

55.17. Purdue is a "registrant". 21 *CFR* § 1300.02(b) as it is a person registered with the DEA under 21 *USC* § 823 requiring registration of all manufacturers of Schedule II controlled substances. Purdue is such a manufacturer.

[105] Katherine Eban, *Oxycontin: Purdue Pharma's Painful Medicine*. Fortune Magazine (Nov. 9, 2011) http://fortune.com/2011/11/09/Oxycontin-purdue-pharmas-painful-medicine/

55.18. Purdue failed to design and operate a system to identify and disclose suspicious orders and failed to notify the appropriate DEA officials upon their discovery.

55.19. Finally in February 2018, Purdue announced that it would cease producing Oxycontin, and would cease marketing it.[106] However, Purdue is unabated in its activities with opioid sales. It is presently pressing opioid sales worldwide using the same nefarious techniques against the brothers and sisters of the Ponca Tribe around the world.[107]

The Purdue companies constitute a racketeer-influenced corrupt organization.

Defendants Janssen Companies

56. The Janssen Companies sold and distributed their manufactured products in Nebraska and to Plaintiff, as well as nationwide. Products sold and distributed by Janssen companies were:

Drug Name	Description	Schedule
Duragesic (Fentanyl)	Opioid analgesic delivered via skin patch; contains gel form of Fentanyl, a synthetic opioid that is up to 100 times more potent than morphine. First approved by FDA August 1990.	II
Mucynta ER (tapentadol hydrochloride)	Opioid agonist; extended-release formulation indicated for severe pain.	II
Nucynta (tapentadol hydrochloride)	Immediate release version of tapentadol hydrochloride for management of moderate to acute severe pain.	II

56.1. Tens of thousands of units of Duragesic Nucynta ER and Nucynta were prescribed in the Ponca Tribe's service areas, and tens of thousands of units

[106] wnpr.org/post/purdue-pharma-and-marketing-Oxycontin.
[107] Fn 45 above.

were prescribed and dispensed pursuant to physician's instructions by providers in the service areas. Plaintiff purchased, inventoried, dispensed, and administered the medications pursuant to lawful doctors' orders after relying on the Janssen Companies' descriptions and accounts of the drugs and their safety.

56.2. Janssen introduced Duragesic in 1990 for "management of pain in opioid tolerant patients, severe enough to require daily, around-the-clock, long term opioid treatment, and for which alternative treatment options are inadequate.

56.3. Nucynta was first approved in 2008 and distributed in tablet form for relief of moderate to severe pain in patients 18 years of age or older. Nucynta ER, marketed beginning in 2011 in tablet form, was for management of pain "severe enough to require daily around-the-clock long term opioid treatment, and for which alternative treatment options are inadequate." This pain indication was later altered to "management of moderate to severe chronic pain in adults", and to "neuropathic pain associated with diabetic peripheral neuropathy ("DPN") in adults. Janssen sold Nucynta and Nucynta ER to a company called Depomed in 2015 for $1.05 billion.

56.4. On October 15, 2000, the FDA warned Janssen that dissemination of "homemade" promotional pieces promoting Duragesic violated the *Federal Food Drug & Cosmetic Act*. A March 30, 2000 second letter from the FDA further warned of this impropriety noting that the promotion pieces

were "false or misleading because they contain misrepresentations of safety information, broadened Duragesic's indication, contained unsubstantiated claims, and lacked fair balance". The March 30, 2000 letter was specific for its violations.[108] The letter was specific in its findings that Janssen was misrepresenting the scope and utility, and benefits and risks of its Duragesic product. It noted that Janssen failed to present "any risk information concerning the boxed warnings, contraindications, warnings, precautions, or side effects with Duragesic's use.[109]

56.5. On September 2, 2004, the US Department of Health & Human Services warned Duragesic in a letter concerning "false or misleading claims about the abuse potential and other risks of the drug, and… unsubstantiated effectiveness claims for Duragesic… including specifically suggesting that Duragesic has a lower potential for abuse compared to other opioid products".

56.6. The September 2004 letter warned Janssen about its claims that a low reported rate of mentions on the Drug Abuse Warning Network ("DAWN") as compared with other opioids was a beneficial indicator, stating this was false or misleading for at least two (2) separate reasons, including the basic fact that DAWN is not a clinical trial database, and the claims are not substantiated by any clinical experience. Other statistical problems were

[108] NDA 19-813 letter from Spencer Salis, US Food & Drug Administration, to Cynthia Chianese, Janssen Pharmaceutical (March 30, 2000)

[109] *Id*.

also identified. Hyperbolic and false claims identified by the September 2004 letter of DHHS were extensive and included false statements about effectiveness for chronic back pain, overall benefits, and reductions in nighttime awakenings, and improvements in disability scores, physical functioning scores, and in social functioning scores.[110]

56.7. On July 15, 2005, the FDA issued a public health advisory warning doctors of deaths resulting from use of Duragesic and its generic competitor manufactured by Mylan NV. The FDA examined circumstances of product use and the possibility "that patients and physicians might be unaware of the risks" of using Fentanyl transdermal patches.

56.8. Despite these letters, Janssen instructed sale representatives, including those working in the Ponca Tribe's service areas and Nebraska, to market Duragesic consistently with the representations identified as false and deceptive. Janssen's inappropriate marketing continued. In 2009, PriCara, a "division of Ortho-McNeil-Janssen Pharmaceuticals, Inc.," sponsored a brochure entitled "Finding Relief: Pain Management for Older Patients" including a DVD by a former actress who played a doctor on a television series. The brochure misrepresented the benefits and falsified the risks and potential adverse effects of Duragesic. It also falsified a list of "partners" interested with Janssen on pain relief issues. Listed were AAPN, American Geriatrics Society, and AGS Foundation for Health & Aging. Janssen

[110] *Id.*

(along with Purdue and Endo) funded AAPN which, in turn, made false claims.

56.9. Janssen disseminated false information about opioids on its website, under the heading Prescribe Responsibly. It was accessible at www.prescriberesponsibly.com until recently. The website's legal notice declares that the content "is owned and controlled by Janssen".[111] The website contains many false or misleading representations including false statements about the relative safety of opioids, risks associated with taking them, and a statement that questions about addictions are often over-estimated and true addiction "occurs only in a small percentage of patients with chronic pain who receive chronic opioid analgesic… therapy."[112]

56.10. The website Prescribe Responsibly also compared risks of opioids favorably with non-steroidal anti-inflammatory drugs ("NSAIDs") such as aspirin and ibuprofen.[113] It repeats scientifically unsupported discussion of pseudo addiction, a syndrome falsified by the Defendants

56.11. Janssen made thousands of dollars in payments to thousands of physicians nationwide, including physicians in the Ponca Tribe's service areas and Nebraska to participate in speakers' bureaus, both to give speeches and pose as doing so for pay-offs, and to provide consulting and market

[111] http//www.prescriberesponsibly.com/legal-notice
[112] *Id*.
[113] *Id*.

assistive services. The amounts expended in Nebraska are believed to exceed $1 million and sales of the products in the State.

56.12. Janssen also failed to report suspicious sales as required as a registrant. Janssen is required to register under 21 USC § 823 and 21 CFR § 1300.02(b) as it manufactured and sold Schedule II controlled substances. It failed to design and operate a system to disclose suspicious orders of controlled substances and failed to notify appropriate DEA field divisions of such activities. This includes activities that occurred in Plaintiff's service areas in Nebraska, or affected the citizens and residents of the Ponca Tribe's service areas and Nebraska, in nearby states.

56.13. Despite the warnings of administrative agencies and overseers, Janssen continued its marketing through false means. It instructed sales representatives across the United States, including the Ponca Tribe's service areas and Nebraska, to market Duragesic as more efficacious, providing better tolerability, and resulting in better patient compliance because it was a patch instead of a pill. The patch was represented as providing better control in the event of patient opioid abuse because patch dosage could not be increased. Sales representatives were aware of patients who increased dosage by applying more than one patch at a time, and aware of abuses resulting from patients freezing and chewing patches to achieve a more rapid introduction of the medication into their bodies. Janssen consciously ignored these circumstances.

56.14. Janssen also misrepresented the risks of opioid addiction, affirmatively stating, in its 2009 PriCara brochure and elsewhere that "many studies show that opioids are rarely addictive when used properly for the management of chronic pain", though it knew this was not accurate.[114] These statements were made concurrently with those on the *Prescribe Responsibly* website.

56.15. On November 4, 2013, the US Department of Justice announced that Johnson & Johnson would pay more than $2.2 billion dollars to resolve criminal and civil liability investigations involving off-label marketing and kickbacks to doctors and pharmacists involving specific medications other than opioids. The specific medications involved were Risperdal, Nivea, and Anterior, but the means and methods of impropriety in the promotion of these antipsychotic drugs, which were misbranded and misrepresented, were substantially identical to the inappropriate means and methods used to promote opioids.

56.16. On April 11, 2012, an Arkansas federal court ordered payment of more than $1.2 billion in fines after a jury found the company minimized or concealed dangers associated with an antipsychotic drug. In January 2012, Janssen Pharmaceuticals settled a Texas case for $158 million, and in South Carolina a judge leveed civil penalties of $327 million against Janssen, while in 2010 a Louisiana jury awarded nearly $258 million.

[114] PriCara brochure, *Finding Relief, Pain Management for Older Adults* (2009).

56.17. In each and all these cases, the manner, means, and methods used by Johnson & Johnson of Janssen, i.e., to hide risks, hyperbolize advantages, mislead physicians and patients.

56.18. Johnson & Johnson has also been fined up to $125 million for violation of the *False Claims Act*, more than $70 million for violations of the *Corrupt Practices Act*, and more than $33 million for drug or medical equipment safety violations. Since 2000, the company is believed to have paid more than **$3 billion** in penalties in the United States for its recurrent wrongful acts and omissions. In December 2017, authorities in France fined Johnson & Johnson $29.62 million after it found the company deliberately slowed market access to generic copies of Duragesic, and when they did so disclosed that Duragesic contains Fentanyl, an opioid which, if misused, can lead to death by overdose. The announcement was widely reported.[115]

56.19. As patients became more addicted to prescription pain killers, a pattern developed of movement to heroin or fentanyl. Fentanyl is more potent and less expensive than heroin, but each has produced a significant increase in overdose deaths nationwide, and the Ponca Tribe's service areas.

56.20. The behaviors of Johnson & Johnson and its subsidiaries are a continuum of criminal and intentional tortious misconduct engaged in by Johnson & Johnson companies for years. In November 2013, two subsidiaries pled guilty to federal felonies. At that time Johnson & Johnson entered into a

[115] Reuters, republished on CNBC, *France Finds Johnson & Johnson about $30,000,000 Over Pain Killer Patch*, https://www.cnbc.com/2017/12/20/france-fines-johnson-johnson-about-30-million-over-painkiller-patch.html

five year corporate integrity agreement and agreed to pay $2.2 Billion in criminal fines and civil penalties and forfeitures for off-label marketing of three antipsychotic drugs. Janssen Pharmaceuticals, Inc. pled guilty to one count of misbranding Risperdal.[116] Also settled were four False Claims Act cases, all in the Eastern District of Pennsylvania. It also settled and paid fines and penalties associated with marketing of Nivea and Anterior, also antipsychotic drugs.

56.21. The sales improprieties leading to the convictions, fines and penalties are substantially identical to those used to market opioids. Johnson & Johnson et al. constitute a racketeer-influenced corrupt organization.

Defendant Endo Companies

57. Defendant Endo Companies sell their manufactured and marketed opioid goods and products in the State of Nebraska to Plaintiff, and nationwide. These include:

Drug Name	Description	Schedule
Opana ER Oxymorphone Hydrochloride	Opioid agonist; extended release tablet. First drug in which Oxymorphone is available in oral extended release formulation. Approved 2006	II
Opana Oxymorphone Hydrochloride	Opioid agonist. Approved 2006	II
Percodan Oxymorphone Hydrochloride & aspirin	Branded tablet combining the three substances. First approved 1950, first marketed by ENDO 2004	II
Percocet Oxymorphone Hydrochloride & Acetaminophen	Branded tablet combining Oxymorphone Hydrochloride and Acetaminophen. First approved 1999. First marketed by ENDO 2006	II
Oxycodone	Generic product	II
Oxymorphone	Generic product	II
Hydromorphone	Generic product	II
Hydrocodone	Generic product	II

[116] *United States of America v. Janssen Pharmaceuticals, Inc.*, No. 13-cr-605, E.D. Pa.

57.1. It is believed that more than 7,500 prescriptions for more than 500,000 units of Opana ER were prescribed in The Ponca Tribe Service area in Nebraska and more than 3,000 prescriptions for more than 175,000 units of Opana ER were prescribed between the years 2012 through 2016. More than one third occurred in Douglas County, a Ponca Tribe service area.

57.2. FDA first approved injectable Opana as indicated "for relief of moderate to severe pain" and "for preoperative medication, support of anesthesia, obstetrical analgesia, and relief of anxiety in patients with dyspnea associated with pulmonary edema secondary to acute left ventricular dysfunction". However, Oxymorphone drugs were removed from the market in the 1970s due to widespread abuse.[117]

57.3. In 2006 tablet form Opana was approved and indicated "for relief of moderate to severe acute pain when the use of an opioid is appropriate". It also approved Opana PR in 2006 as an extended release tablet version of Opana. ENDO's goal was to use Opana ER to take market share from Oxycontin. It marketed Opana ER as safer with less abuse potential because of its crush resistance as compared with Oxycontin.

57.4. Endo's annual sales of Opana and Opana ER were several hundred million dollars per year, growing rapidly from $100.7 million in 2007 to more than $380 million in 2011.

[117] John Fauber, et al. *Opana gets FDA Approval Despite History of Abuse, Limited Effectiveness in Trials*, Milwaukee Journal Sentinel (May 9, 2015).

57.5. In December 2011, Endo commenced to claim that an Opana ER reformulation offered safety advantages over the original because the latter "is resistant to crush by common methods and tools employed by abusers of opioids… [and] is less likely to be chewed or crushed even in situations where there is no intent for abuse" such as inadvertent chewing. Endo then describes it reformulated Opana ER as crush resistant. In a December 2011 press release announcing FDA approval, these benefits were touted.

57.6. However, in December 2012, the Federal CDC issued a health alert noting that fifteen (15) people in Tennessee contracted thrombocytopenic purpura, a rare blood clotting disorder, after use of reformulated Opana ER. Endo responded that it would look into the data but was not especially concerned because of the "very distinct area of the country" where it occurred.[118]

57.7. Shortly thereafter the FDA determined that ENDO's conclusions about purported safety advantage of reformulated Opana ER were unfounded. On May 10, 2013, ENDO received the FDA's letter finding the Opana ER was vulnerable to "cutting, grinding, or chewing" and can be prepared for insufflation (snorting) with common tools and methods. The FDA also warned that it could be readily prepared for injection.

57.8. On February 21, 2014, Endo Pharmaceuticals reached a resolution of criminal and civil claims with federal and participating state authorities. The settlement resolved a previously disclosed investigation concerning

[118] Jake Harper, et al., *How a Pain Killer Designated to Deter Abuse Helped Spark an HIV Outbreak, National Public Radio* (April 1, 2016).

past US sales, marketing and promotional practices. Endo entered into a Deferred Prosecution Agreement with the United States Department of Justice for a period of 2.5 years, and a separate Corporate Integrity Agreement with the United States Department of Health and Human Services, office of Inspector General, for a period of 5 years.[119] Endo Health Solutions, Inc., and its subsidiary Endo Pharmaceuticals Inc. agreed to pay $192.7 million to resolve criminal and civil issues involved its Lidoderm product. In the deferred prosecution agreement to resolve criminal charges against it, Endo Pharmaceuticals, Inc. admitted that it intended that Lidoderm be used for unapproved indications and that it promoted Lidoderm to health care providers for those unimproved uses.[120]

57.9. The Endo companies used these wrongful practices to sell and distribute their opioid products in the Ponca Tribe's service areas and Nebraska.

Defendant, Cephalon / Teva Companies

58. Defendants Cephalon and the Defendant Teva companies sold their products and did business here and with Plaintiff. It also conducted sales activities, including deceptive once, like those disclosed below, here. These Defendants are "registrants under 21 CFR §1300.02(b) and 21 USC § 823 as manufacturers and distributors of opioid medications.

[119] This is admitted on Endo's website at http://www.endo.com/endopharma/about-us/corporate-compliance

[120] Press release of US DOJ https://www.justice.gov/opa/pr/endo-pharmaceuticals-and-endo-health-solutions-pay-1927-million-resolve-criminal-and-civil

58.1. The Teva Companies including Cephalon knew and admitted that the only United addiction epidemic has had a dramatic adverse impact on the United States and the world. On its website the Captiva Companies acknowledge:

> Opioids are the most prescribed medications for the treatment of both acute and chronic pain. Originally used to treat cancer-related pain, their use has expanded over the past 10 to 15 years to the treatment of chronic non-cancer pain.
>
> The impact of opioid abuse is staggering. In the US alone, 1 in 20 over the age of 12 has abused opioid medications*. This results in nearly 15,000 overdose deaths per year**, an increase of more than 400% in the decade from 1999-2009, as well as nearly 1M emergency room visits in 2010.[121]

58.2. Cephalon misrepresented studies that produced outcomes supportive of sales, but conceal that they were biased, flawed, or based on inadequate information.it also concealed that many studies were sponsored by Cephalon/Teva, and paid large sums of money to key opinion leaders markets, including the market where Plaintiff are located. The studies were falsified.[122]

58.3. Cephalon/Teva sponsored continuing medical education events and presentations for positions over a long period of time dating back to at least 2003. In that year, he presented CM the materials titled "*Pharmacologic Management of Breakthrough or Incident Pain*". It described a chronic pain as under treated and complained that overview a medications were

[121] http://www.tevapharm.com/research_development/rd_focus/pain/ citing ** Centers for Disease Control and Prevention. (2011). Morbidity and Mortality Weekly Report.

[122] Carreyyou, Cephalon Used Improper Tactics.

stigmatized with the often unfounded and self-imposed decision here of dealing with the highly regulated distribution system for opioid analgesics [calling them] a barrier to effective pain management."[123]

58.4. In 2003 former Cephalon employees filed whistleblower lawsuits in which they alleged that Cephalon wrongfully marketed its opioid product called Actiq for unapproved, off-label uses. On September 29, 2008, Cephalon finalized and entered into a "Corporate Integrity Agreement" with the Office of the Inspector General of HHS. Cephalon is believed to have done so to limit losses and protect senior personnel from criminal investigations and prosecution. The company agreed to pay $425 million in civil and criminal penalties for its off-label marketing of Actiq and two other drugs (Gabitril and Provigil). Cephalon wrongfully trained sales representatives to disregard FDA-approved label restrictions on approved use of Actiq and the other two drugs, and hired sales people and KOLs in medicine to speak to physicians about off-label uses of the drugs. It also funded CMEs to promote off-label uses.[124]

58.5. Cephalon/ Tiva are "registrants" under the Act. They are obligated to design and operate and to design a system to disclose to the registrant suspicious orders of controlled substances and to notify the US Drug

[123] Michael J. Brennan, *et al.*, *Pharmacologic Management of Breakthrough or Incident Pain*, Medscape, http://www.medscape.org/viewarticle/449803 (last visited Oct. 10, 2017).

[124] The US DOJ described the wrongful conduct in a Press Release, US Department of Justice, Pharmaceutical Co. Cephalon 2 Pay 425 million 4 Off-Label Drug Marketing (September 29, 2008), https://www.Justice.gov/archives/usao/pae/News/2008/sep/cephalonrelease.pdf

Enforcement Agency and its field division office of its area of any suspicious activity. Cephalon/Tiva failed to design or operate the system to disclose suspicious orders of controlled substances. They also failed to report as required by law.

58.6. In 2008, Cephalon entered in to a Corporate Integrity Agreement with the Inspector General of DHHS and agreed to pay a fine of $425 million for its manner and methods in marketing Actiq, Gabitril and Provigil for use is not approved by the FDA. Its wrongful conduct included abuse of ties to doctors in the nature of Key Opinion Leader payoffs. It was required to post its links to doctors under the terms of the CIA Corporate Integrity Agreement for the years 2009 through 2012. When the Agreement expired it promptly ceased doing so, but before its cessation, it reported nearly $90 million in payments to doctors.[125] These payments were part of the scheme with other Defendants and within the Cephalon/Teva companies to flood the market with unlawful dosages of its opioid products.

58.7. Cephalon/Teva used sponsored CME presentation to promote use of its opioid products for "off label" or unapproved uses.[126]

Defendant Insys

59. Insys engages in the sale of its opioid pharmaceutical drugs in The Ponca Tribe Service area in Nebraska and sells and distributes Subsys, a fentanyl sublingual

[125] https://www.propublica.org/article/freed-of-disclosure-requirement-drug-maker-pulls-doctor-payments-offline

[126] Stephen H. Landy, *Oral Transmucosal Fentanyl Citrate for the Treatment of Migraine Headache Pain In Outpatients: A Case Series*, 44(8) Headache (2004), http://www.medscape.com/viewarticle/488337_2).

spray; semi-synthetic opioid agonist, approved in 2012 and constituting a Schedule II drug. It is sold as a breakthrough pain medication for cancer patients 18 years of age and older who are already receiving treatment. Insys revenues are derived almost entirely from sale of this Subsys product. In fact, in 2015, Insys reported to the US SEC that $329.5 million of $331 million in total sales was derived from Subsys. More than 6,000 units of the product are believed to of been sold in Nebraska. Doctors associated with Plaintiff prescribed the patients including those insured by Medicare Part D.

59.1. Insys sold its Subsys product primarily through Defendants AmerisourceBergan, McKesson and Cardinal Health. They accounted for more than 50% of Subsys sales in 2015.

59.2. Insys achieved premature and inappropriate administrative approval of it Subsys opioid medication by manipulating the FDA prior authorization process, misleading pharmacy benefit managers about the role of Insys in the prior authorization process, and representing its product as a breakthrough cancer pain medication. These facts were found and determined by a U.S. Senate investigative committee.[127]

59.3. Fentanyl products like Subsys are "the most potent and dangerous opioids on the market."[128] However, Insys did not disclose these risks and in fact minimize them and trained and instructed sales representatives to use false descriptions of mild-to-severe pain as the worst outcome for patients in

[127] McCaskill, HSGAC Minority Staff Rpt, Insys Therapeutics & Systemic Manipulation of Prior Authorization (2017).

[128] D. Gusovsky, *The Pain Killer: a Drug Company Putting Profits Above Patients*, http://www.cnbc.com/2015/11/04/thedeadly- drug-appeal-of-insys-pharmaceuticals.html.

otherwise stable persistent pain.[129] They marketed around the most knowledgeable physicians, oncologists, encouraging use of the product by dentists, podiatrists, as well as pain physicians.[130]

59.4. On December 8, 2016, the United States Attorney for the District of Massachusetts announced the criminal indictments of Insys former CEO and president and former vice presidents of sales, and managed markets, and several former regional sales directors.[131] Charges include violations of the federal Anti-Kickback Law, and criminal RICO including conspiracy to commit wire and mail fraud, as well as allegations of bribery and defrauding of insurers.[132]

59.5. The Indictment correctly details a coordinated central scheme by Insys conducted by Insys personnel in coordination with others. It also alleges and describes bribes to physicians, sham speakers euros, and use of speakers' bureaus to pay practitioners to prescribe Subsys. Often the speakers' bureaus were simply dinners at fancy restaurants with no speaking event, no guests, but falsified appearances to document the occasions. Events of this kind occurred in the Ponca Tribe's service areas.

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129 Insys misused a publication in these efforts. That publication which was misused is R K Portenoy et al., *Pain: Definition, Prevalence and Characteristics* 41(3) Pain 273-81 (July 1990).

130 This was reported publicly by *New York Times* contributor Katie Thomas (May 13, 2014).

131 John Kapoor, Phoeniz AZ, Michael L. Babich, of Scottsdale, Ariz., former CEO and President of the company; Alec Burlakoff, of Charlotte, N.C., former Vice President of Sales; Richard M. Simon, of Seal Beach, Calif., former National Director of Sales; former Regional Sales Directors Sunrise Lee, of Bryant City, Mich., and Joseph A. Rowan, of Panama City, Fla.; and former Vice President of Managed Markets, Michael J. Gurry, of Scottsdale, Ariz were indicted. https://www.fda.gov/ICECI/CriminalInvestigations/ucm582374.htm

132 Press Release, U.S. Attorney's Office for the District of Massachusetts, Pharmaceutical Executives Charged in Racketeering Scheme (Dec. 8, 2016),https://www.justice.gov/usao-ma/pr/pharmaceutical-executives-charged-racketeeringscheme

Defendant Mallinckrodt

60. Mallinckrodt, including Mallinckrodt PLC, and Mallinckrodt Pharmaceuticals, engages in the sale and distribution of its manufactured pharmaceutical drugs in Nebraska and to Plaintiff. Mallinckrodt is the largest US supplier of opioid medications and among the top ten (10) generic pharmaceutical manufacturers in the United States based on prescriptions. Mallinckrodt drugs include:

Drug Name	Description	Schedule
Exalgo (hydromorphone, hydrochloride extended release)	Opioid agonist indicated for opioid-tolerant patients for management of pain severe enough to require daily around-the-clock long term opioid treatment and for which alternative treatment options are not adequate	II
Roxicodone (oxycodone hydrochloride)	Brand name instant-release form of oxycodone hydrochloride. Indicated for management of pain severe enough to require an opioid analgesic for which alternative treatments are inadequate. Acquired from Xanodyne Pharmaceuticals in 2012. Nicknames include Roxies, Blues, & Stars	I
Xartemis XR (oxycodone hydrochloride & acetaminophen	Approved by FDA March 2014 for management of acute pain severe enough to require opioid treatment and in patients for whom alternative treatment options were ineffective, not tolerated, or otherwise inadequate. This was the first extended release oral combination of oxycodone and acetaminophen.	II
Methadose (methadone hydrochloride)	Branded generic opioid product. Opioid antagonist indicated for treatment of opioid addiction.	II
Morphine Sulfate Extended release	Generic product.	II
Fentanyl Extended release	Generic product	II
Fentanyl Citrate	Generic product	II
Oxycodone & acetaminophen	Generic product	II
Hydrocodone bitartrate & acetaminophen	Generic product	II
Hydrochloride	Generic product	II

Hydromorphone hydrochloride Extended release	Generic product	II
Naltrexone hydrochloride Extended Release	Generic product	II
Oxymorphone	Generic product	II
Methadone hydrochloride	Generic Product	II
Oxycodone hydrochloride	Generic Product	II

60.1. After purchasing Roxicodone from Sandu Pharmaceuticals in 2012, Mallinckrodt commenced its distribution in September 2014 at a trade show known as *PAIN Week* in Las Vegas. Its opioids were widely prescribed in Nebraska. It was prescribed by physicians associated with the Plaintiff Hospitals in reliance upon Mallinckrodt's representations and statements, ordered, inventoried, dispensed, and pursuant to physicians' orders administered Xartemis and other Mallinckrodt products.

60.2. Mallinckrodt provided substantial funding to purportedly neutral organizations which disseminated false messages about opioids. These events are described for all participating Defendants separately in this complaint. Until at least February 2009, Mallinckrodt provided an educational grant to pain-topics.org, a now defunct website that touted itself as a "noncommercial resource for healthcare professionals, providing open access to clinical news, information, research, and education for a better understanding of evidence based on pain management practices.[133]

60.3. The website included a document entitled "Oxycodone Safety Handout for Patients" containing false statements associated with opioids, including a

[133] Pain treatment topics, paintopices.org, https://web.archive.org/web/20070104235709/http://www.pain-topics.org:80/

response to the question, "Will you become dependent or addicted to oxycodone?" Mallinckrodt responded to this by assuring patients that a sudden cessation would cause them to experience uncomfortable withdrawal symptoms which might take several days to develop. These included diarrhea, body aches, weakness, restlessness, anxiety, loss of appetite, etc., but assured patients that "this is not the same as addiction, a disease involving craving for a drug, loss of control over taking it or compulsive use and using it despite harm." [134] In addition, under Mallinckrodt's sponsorship, pain-topics.org published information about pseudo addiction. Touting it as a medical condition, though there was no such condition, and describing it, commencing in 2001 and continuing for years thereafter, as "aberrant patient behaviors that may occur when pain is undertreated", along with other misleading statements.[135]

60.4. Mallinckrodt published other false information to the public to suggest that generic oxycodone was less prone to abuse than the branded product.[136]

60.5. In November 2016, Mallinckrodt paid Dr. Scott Gottlieb, new Commissioner of the FDA, at least $22,500 for a speech in London shortly after the US Presidential election. Gottleib also received money from Health Distribution Alliance, an industry-funded organization that pushes

[134] *Id*.
[135] FAQs, paintopics.org, http://web.archive.org/web/20070709031530/http://www.paintopics.org:80/faqs/index1.php#tolerance.
[136] Lee A. Caral, *Commonsense Oxycodone Prescribing and Safety*, paintopics.org (June 2017). http://paincommunity.org/blog/wp-content/uploads/OxycodoneRxSafety.pdf.

the agenda of large pharmaceutical wholesalers and is often critical of regulations of the pharmaceutical opioid market. *Id.* Mallinckrodt made payments to thousands of physicians including physicians in Nebraska. It widely distributed its products in the Ponca Tribe's service areas.

60.6. In 2008, DEA and federal prosecutors investigated Mallinckrodt and uncovered that Mallinckrodt sent large quantities of its products in inexplicable dosage levels and amounts to only a few locations where abuses were, or should have been, obvious to any reasonable observer. For example, Five hundred thousand tablets of oxycodone were sent to Florida, representing 66% of all oxycodone sold in the state. Mallinckrodt was found to have conspired with distributors to achieve these objectives. These were widely exposed to the public in the press.[137]

60.7. Even during the investigation, Mallinckrodt's false activities continued. In April 2017 Mallinckrodt reached an agreement with DEA and the US Attorney for the Eastern District of Michigan and Northern District of New York to pay $35,000,000 to resolve the probe into distribution of its opioid medications.[138] Mallinckrodt settled while admitting no wrongdoings.[139]

60.8. Mallinckrodt was a registrant[140] with the FDA. As a registrant, it was obligated to design and operate a system to disclose to registrants

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137 Lenny Bernstein et al., the Government's Struggle to Hold Opioid Manufacturers Accountable, Washington Post (April 2, 2017).

138 Press release US Department of Justice, Mallinckrodt Agrees to Pay $35,000.00 Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Record Keeping Violations (July 11, 2017).

139 *Id*.

140 21 *CFS* § 1300.02(b) incorporating 21 *USC* § 823 requiring manufacturers of Schedule II controlled substances

suspicious orders of controlled substances and require notification of the FDA.[141] Mallinckrodt breached these duties. Excess medications were shipped into The Ponca Tribe's service areas and Nebraska, reached the hands of users who became addicted and dependent, and required services from Plaintiff for which financial losses were sustained.

Pharmaceutical Defendants' Wrongful Conduct

61. In addition to the wrongful acts alleged above, each Pharmaceutical Defendant developed a well-funded, sophisticated, and deceptive marketing and/or distribution scheme targeted at consumers and physicians with false and misleading messages about the safety and efficacy of opioids. These Defendants used direct marketing, as well as veiled advertising by surrogates posing as objective persons to spread false and deceptive statements about the risks and benefits of long-term opioid use The Pharmaceutical Defendants intended to, and did, create the "new" market for prescription opioids. They overrode and supplanted standard medical practice with prolific declarations of the medicinal safety and value of opioids though the Pharmaceutical Defendants knew the statements were gross exaggerations, and contradictions, of pharmacological facts and known circumstances and experiential results. The statements are unsupported by and contrary to scientific evidence. These statements were also contrary to pronouncements by and guidance from the FDA and U.S. Center for Disease Control.

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to register with DEA.

[141] 21 *CFR* § 1301.74(b).

62. The Pharmaceutical Defendants targeted uninformed medical practitioners, susceptible prescribers and vulnerable patient populations, including those in Nebraska. In addition, the Pharmaceutical Defendants allowed word to be released that some opioids, including Oxycontin with time-release features, could have time-release features overcome by simply crushing the tablets containing them. This turned them into an extraordinary dangerous addictive substance with many of the properties of heroin.

63. The Pharmaceutical Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients in Nebraska. They caused or permitted word of how to overcome time release features through the Distribution Defendants and the Pharmacy Defendants. All Defendants deployed seemingly unbiased and independent third parties as well as their own personnel, to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout geographic areas and patient demographics of Nebraska. They did so while simultaneously make no reasonable efforts to establish, maintain or operate protocol to monitor distribution, identify diversion, and cut off improper travel of their products through the stream of commerce and into the hands of unknowing, unintended, or inappropriate and unattended recipients and users.

64. The Pharmaceutical Defendants' branded advertisements deceptively portrayed the benefits of opioids for chronic pain. These are examples of how this was done:

64.1. Defendant Purdue ran a series of ads, called "Pain Vignettes," for Oxycontin that featured chronic pain patients and recommended Oxycontin

for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that Oxycontin would help the writer work effectively.

64.2. Defendant ENDO distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs, misleadingly implying that the drug would provide long-term pain-relief and functional improvement.

64.3. Endo and Purdue agreed in 2015-16 to stop these particularly misleading representations in New York, but they continued to disseminate them in Nebraska. Finally on June 8, 2017, the FDA requested removal of Opana ER from the market for risks related to abuse.[142] As the FDA announced: "This is the first time the agency has taken steps to remove a currently marketed opioid pain medication from sale due to the public health consequences of abuse."[143]

65. The Pharmaceutical Defendants and the Distribution Defendants, and Pharmacies, promoted the use of opioids for chronic pain through "detailers" – sophisticated and specially trained sales representatives who visited individual medical doctors and other providers, using "detail" vendors who hosted physicians, offered incentives, encouraged usage of their opioids, present the false narratives of the Pharmaceutical Manufacturers and represented to physicians and others that their care practices would not conform to professional standards unless they prescribed and aided distribution of opioids. In 2014, these Defendants spent almost $200 million on detailing

[142] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm
[143] *Id.*

branded opioids to healthcare providers. Much of this money and effort was spent in Nebraska. As early as 2009, peer reviewed publications started to appear, but were drowned by Defendants' commercial efforts, warning that the promotion and marketing of opioids was a commercial triumph, but a public health tragedy.[144]

66. The FDA cited at least one of these Defendants for deceptive promotions by its detailers and direct-to-physician marketing. In 2010 an FDA-mandated "Dear Doctor" letter required Actavis to inform doctors that "Actavis sales representatives distributed . . . promotional materials that . . . omitted and minimized serious risks associated with [Kadian]," including the risk of "[m]isuse, [a]buse, and [d]iversion of [o]pioids" and, specifically, the risk that "[o]pioid[s] have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion."[145] Also in 2010, the FDA demanded a reformulation of Oxycontin to address the problem caused by breaking its tablet form into powder.[146]

67. The Pharmaceutical Defendants invited prescribers of medications and pharmacies to participate, for payment and other remuneration, on and in speakers' bureaus and programs paid for by these Defendants. These speaker programs were designed to provide incentives for doctors to prescribe opioids, including recognition and compensation for being selected as speakers. Speakers were required to, and did, repeat the false narratives of the Pharmaceutical Defendants. The Distribution Defendants

144 Art Van Zee, *The Promotion & Marketing of Oxycontin: Commercial Triumph, Public Health Tragedy*, 99 Am Public Health J 221-227 (Feb 2009). Accessible at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/

145 FDA Warning letter at https://www.fdaNews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf

146 https://wayback.archive-it.org/7993/20170112130258/http:/www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm207480.htm

cooperated in these improper actions. Recruited speakers often unwittingly imparted to audiences, the false impressions of pharmacologically proven facts and data and corroborative clinical trials and observations when, in fact, this was not true. Instead, they presented scripted talks prepared by these Defendants and including their false narratives. These presentations conveyed misleading information, omitted material information, and failed to correct Defendants' prior misrepresentations and institutional knowledge, about the risks and benefits of opioids. The Distribution Defendants participated with the Pharmaceutical Defendants in these efforts.

68. These sales efforts by "detail" vendors were direct, personalized, and highly effective. It promoted the nationwide proliferation of prescription opioids and persuaded the medical community that opioids were within the standard of medical care for many uses and patients for which they were entirely inappropriate. Defendants used sophisticated data mining and intelligence to track and understand the rates of initial prescribing and renewal by individual doctors, allowing specific and individual targeting, customizing, and monitoring of their marketing. This also facilitated incentive programs that further reinforced the false narratives of the Pharmaceutical Defendants in Nebraska and elsewhere. The Pharmaceutical and Distribution Defendants also trained at least 5,000 physicians between 1996 and 2001 to serve as key opinion leaders, known as KOLs, to influence prescribing patterns and compel belief among health practitioners that Oxycontin and similar opioids were safe, when they were not.[147]

[147] Fn 29, above.

69. The Pharmaceutical Defendants deceptively marketed opioids in the Ponca Tribe's service area and in Nebraska, through unbranded advertising that promoted opioid use generally, yet silent as to a specific opioid. This advertising was ostensibly created and disseminated by independent third parties, but funded, directed, coordinated, edited, and distributed, by these Defendants and their public relations firms and agents.

70. The Pharmaceutical Defendants used putative third-party, unbranded advertising to avoid regulatory scrutiny as such advertising which was not submitted to or reviewed by the FDA. Defendants used third-party, unbranded advertising to create the false appearance that deceptive messages came from independent and objective sources.

71. The Pharmaceutical Defendants' deceptive unbranded marketing also contradicted their branded materials reviewed by the FDA. They buried, and concealed from the professional public and the consuming public, the true facts. The Pharmaceutical Defendants marketed opioids through a small circle of doctors who were vetted, selected, funded, and promoted by these Defendants because their public positions supported the use of prescription opioids to treat chronic pain. These doctors became known as "key opinion leaders" or "KOLs." These Defendants paid KOLs to serve in a number of doctor-facing and public-facing capacities, all designed to promote a pro-opioid message and to promote the opioid industry pipeline, from manufacture to distribution to retail. These efforts also falsified but spread widely, false information and data about opioids and the care of patients with them.

72. These Defendants entered into and/or benefitted from arrangements with seemingly unbiased and independent organizations or groups that generated treatment

guidelines, unbranded materials, and programs promoting chronic opioid therapy, including the American Pain Society ("APS"), American Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), American Society of Pain Education ("ASPE"), National Pain Foundation ("NPF"), and Pain & Policy Studies Group ("PPSG"). These groups proved to be "front" organizations, created, expanded, or seduced by incentives and falsehoods, to reinforce the false opioids narratives and advance the improper and abusive commercial objectives of the Pharmaceutical Defendants. The Pharmaceutical Defendants collaborated, through these front organizations and groups, to spread deceptive messages about the risks and benefits of long-term opioid therapy.

73. To convince doctors and patients in the Ponca Tribe's service area and in Nebraska that opioids can and should be used to treat chronic pain, the Pharmaceutical Defendants had to persuade them that long-term opioid use is both safe and helpful. This could not be done without deceptions. These Defendants made and widely disseminated claims that were not supported by or were contrary to scientific evidence and contradicted by data.

74. To convince doctors and patients that opioids are safe, the Pharmaceutical Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively discredited by the FDA[148] and CDC.[149] These misrepresentations – which

[148] FDA Opioids Action Plan: https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm484714.htm
[149] CDC Fact Sheet: https://www.cdc.gov/drugoverdose/pdf/guidelines_at-a-glance-a.pdf

are described below – reinforced each other and created these false beliefs among targeted and duped healthcare providers:

(a) Starting patients on opioids were low-risk because most patients would not become addicted, and because those who were at greatest risk of addiction could be readily identified and managed;

(b) Patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs;

(c) The use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and

(d) Abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive.[150]

The Pharmaceutical Defendants did, and still do, make these misrepresentations now and will continue to do so unless enjoined.[151] These falsehoods misrepresent the dangers and addictive risks of opioids and help keep them in the stream of commerce, causing more mothers to become addicted, more fetuses to be affected, more newborns to suffer NAS, and more permanent harm to more people to be inflicted, every day. These falsehoods

[150] Some examples of these false and deceptive claims by opioid manufacturers are: (a) Actavis employed a patient education brochure that falsely claimed opioid addiction is "less likely if you have never had an addiction problem"; (b) Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain, falsely claiming that addiction is rare and limited to extreme cases of unauthorized doses; (c) ENDO sponsored a website, Painknowledge.com, which falsely claimed that "[p]eople who take opioids as prescribed usually do not become addicted"; (d) ENDO distributed a pamphlet with the ENDO logo entitled Living with Someone with Chronic Pain, which stated that: "most people do not develop an addiction problem"; (e) Janssen distributed a patient education guide entitled Finding Relief: Pain Management for Older Adults which described as "myth" the claim that opioids are addictive; (f) a Janssen website falsely claimed that concerns about opioid addiction are "overestimated"; (g) Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* – that falsely claims that pain is undertreated due to "misconceptions about opioid addiction."

[151] The risk of this exploitation by Defendants become an international foreign affairs crisis is real. See fn 45.

pose grave risks of irreparable harm to Plaintiff. Damages are necessary, but alone, neither damages nor any other remedy at law is adequate.

75. These claims are contrary to scientific evidence, as the FDA and CDC have conclusively declared. As noted in the 2016 CDC Guideline endorsed by the FDA, there is "extensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction])." The Guideline points out that "[o]pioid pain medication use presents serious risks, including . . . opioid use disorder" and that "continuing opioid therapy for three (3) months substantially increases risk for opioid use disorder."[152] In September 2017, the FDA imposed stringent new requirements on the Pharmaceutical Defendants.[153]

76. The FDA further exposed the falsity of the Pharmaceutical Defendants' claims about the low risk of addiction when it announced changes to the labels for certain opioids in 2013 and for other opioids in 2016. In its announcements, the FDA found that "most opioid drugs have 'high potential for abuse'" and that opioids "are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death." According to the FDA, because of the "known serious risks" associated with long-term opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death," opioids should be used only "in patients for whom alternative treatment options"

[152] The CDC Guideline for Prescribing Opioids is found at: https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

[153] In September 2017, the FDA issued letters notifying 74 manufacturers of immediate release (IR) opioids that their drugs are now subject to more stringent requirements under a Risk Evaluation and Mitigation Strategy (REMS). https://blogs.fda.gov/fdavoice/index.php/2017/09/fda-takes-important-steps-to-stem-the-tide-of-opioid-misuse-and-abuse/

like non-opioid drugs have failed. The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction "can occur in patients appropriately prescribed [opioids]."[154]

77. The State of New York, in a 2016 settlement agreement with Endo, found that opioid "use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder." ENDO had claimed on its www.opana.com website that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted," but the State of New York found no evidence for that statement. Consistent with this, ENDO agreed not to "make statements that . . . opioids generally are non-addictive" or "that most patients who take opioids do not become addicted" in New York. This agreement, however, did not extend to Nebraska or Plaintiff, and ENDO did not change its conduct here.

78. The Pharmaceutical Defendants falsely instructed doctors and patients that the signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. Defendants called this phenomenon "pseudo-addiction" – a term used by Dr. David Haddox, who went to work for Purdue, and Dr. Russell Portenoy, a KOL for Cephalon, Endo, Janssen, and Purdue. Defendants falsely claimed that pseudo-

[154] *Id.* The FDA cautioned*:* "America is awash in immediate-release (IR) opioids. About 90 percent of all opioid pain medications prescribed – or 160 million prescriptions a year – are for IR formulations like hydrocodone and acetaminophen or oxycodone and acetaminophen combinations. Many people who are currently addicted to opioids became medically addicted. Their first exposure to opioids was from a legal prescription, and for many, that prescription was written for an IR formulation of these drugs. Many addicted patients may then move on to higher dose formulations or more accessible illegal street drugs."

addiction was substantiated by scientific evidence.[155] The 2016 CDC Guideline rejected "pseudo-addiction", explaining that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use," and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit." Defendant's coined and propagated the term "pseudo-addiction" though the term was not one known to medicine before the defendants embarked upon their deceptive campaign.[156]

79. The Pharmaceutical Defendants falsely instructed doctors and patients that addiction risk screening tools, patient agreements, urine drug screens, and similar strategies were very effective to identify and safely prescribe opioids to even those patients predisposed to addiction. These misrepresentations were reckless because Pharmaceutical Manufacturers and Distributors know of deceptive and misleading testing, testimonials and publications as they sponsored and promoted them, and conceived and implemented the plan to launch them. To maximize probable success with these reckless statements, Defendants directed opioids patients to family doctors who

[155] Some examples of these deceptive claims are: (a) Cephalon and Purdue sponsored Responsible Opioid Prescribing, which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudo-addiction, rather than true addiction; (b) Janssen sponsored, funded, and edited the Let's Talk Pain website, which in 2009 stated: "pseudo-addiction . . . refers to patient behaviors that may occur when pain is under-treated"; (c) ENDO sponsored a National Initiative on Pain Control (NIPC) CME program titled Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia, which promoted pseudo-addiction by teaching that a patient's aberrant behavior was the result of untreated pain; (d) Purdue sponsored a deceptive CME program entitled Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse in which a narrator notes that because of pseudo-addiction, a doctor should not assume the patient is addicted.

[156] "Pseudo-addiction" is not a term found in additions of these well-known medical dictionaries published prior to 1999: Stedman*'s Concise Medical Dictionary for the Health Professions* (3d Ed. 1998); and even today it is not a listed term on the dictionary of www.webmd.com.

lack the time and expertise to closely manage higher-risk patients on opioids, and to develop expertise with opioids substances. They also targeted these doctors with presentations by KOLs, or new they were so targeted by manufacturers, to lull them into a sense of security with the use of opioids. Pharmaceutical Defendants' misrepresentations were intended to make doctors comfortable prescribing opioids.[157]

80. The 2016 CDC Guideline exposes the falsity of these misrepresentations, noting that there are no studies assessing the effectiveness of risk mitigation strategies – such as screening tools, patient contracts, urine drug testing, or pill counts widely believed by doctors to detect and deter abuse – "for improving outcomes related to overdose, addiction, abuse, or misuse." The Guideline emphasizes that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."

81. To conceal or understate the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, Pharmaceutical Defendants falsely claimed that opioid dependence can easily be solved by tapering, that opioid withdrawal was not difficult, and that there were no problems in stopping opioids after long-term use.

82. A CME sponsored by Endo, entitled Persistent Pain in the Older Adult, claimed that withdrawal symptoms could be avoided by tapering a patient's opioid dose

[157] Some examples of these deceptive claims are: (a) an ENDO supplement in the Journal of Family Practice emphasized the effectiveness of screening tools to avoid addictions; (b) Purdue's webinar, Managing Patient's Opioid Use: Balancing the Need and Risk, claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths"; (c) Purdue represented in scientific conferences that "bad apple" patients – and not opioids – were the source of the addiction crisis, when in fact the "bad apples" were the Defendants.

by up to 20% for a few days. Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management, that claimed "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," without mentioning any known or foreseeable issues.

83. Pharmaceutical Defendants deceptively minimized the significant symptoms of opioid withdrawal – which, as explained in the 2016 CDC Guideline, include drug cravings, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia (rapid heartbeat), spontaneous abortion and premature labor in pregnant women, and the unmasking of anxiety, depression, and addiction – and grossly understated the difficulty of tapering, particularly after long-term opioid use.

84. The 2016 CDC Guideline recognizes that the duration of opioid use and the dosage of opioids prescribed should be "limit[ed]" to "minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms," because "physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days." The Guideline further states that "tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence" and highlights the difficulties, including the need to carefully identify "a taper slow enough to minimize symptoms and signs of opioid withdrawal" and to "pause[] and restart[]" tapers depending on the patient's response. The CDC also acknowledges the lack of any "high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are

discontinued."[158] These facts and findings were contradicted, disputed, and denied by the Pharmaceutical Defendants and the Distributor Defendant's and the Pharmacy Defendants for many years before, and even after, issuance of the Guidelines. These contradictions, disputes and denials occurred notwithstanding the fact that the Defendants were aware of their ongoing campaigns of distortion, concealment, misstatement of personal physician experiences, and efforts to oversell opioids.

85. The Pharmaceutical Defendants falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk of addiction and other health consequences, and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief.[159]

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[158] The CDC Guideline for Prescribing Opioids is found at: https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

[159] For example: (a) an Actavis patient brochure stated - "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction"; (b) Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain, claiming that some patients need larger doses of opioids, with "no ceiling dose" for appropriate treatment of severe, chronic pain; (c) an ENDO website, painknowledge.com, claimed that opioid dosages may be increased until "you are on the right dose of medication for your pain"; (d) an ENDO pamphlet Understanding Your Pain: Taking Oral Opioid Analgesics, stated "The dose can be increased. . . . You won't 'run out' of pain relief"; (e) a Janssen patient education guide Finding Relief: Pain Management for Older Adults listed dosage limitations as "disadvantages" of other pain medicines yet omitted any discussion of risks of increased opioid dosages; (f) Purdue's In the Face of Pain website promotes the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will; (g) Purdue's *A Policymaker's Guide to Understanding Pain & Its Management* stated that dosage escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high opioid dosages; (h) a Purdue CME entitled Overview of Management Options taught that NSAIDs and other drugs, but not opioids, were unsafe at high dosages; (i) Purdue presented a 2015 paper at the College on the Problems of Drug Dependence challenging the correlation between opioid dosage and overdose.

86. These and other representations conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage." More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages." The CDC states that "there is an increased risk for opioid use disorder, respiratory depression, and death at higher dosages." That is why the CDC advises doctors to "avoid increasing dosages" above 90 morphine milligram equivalents per day.[160]

87. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." The FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality."[161]

88. Pharmaceutical Defendants' deceptive marketing of the "abuse-deterrent properties" of some of their opioids created false impressions that these opioids can curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less addictive.

89. Pharmaceutical Defendants made misleading claims about the ability of their so-called abuse-deterrent opioid formulations to deter abuse. For example, Endo's advertisements for the 2012 reformulation of Opana ER falsely claimed that it was

[160] See Fn 41.
[161] *Id.*

designed to be crush resistant, in a way that suggested it was more difficult to abuse. The FDA warned in a 2013 letter that there was no evidence Endo's design "would provide a reduction in oral, intranasal or intravenous abuse." Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed.

90. In a 2016 settlement with the State of New York, ENDO agreed not to make statements in New York that Opana ER was "designed to be, or is crush resistant." The State found those statements false and deceptive because there was no difference in the ability to extract the narcotic from Opana ER. Similarly, the 2016 CDC Guideline states that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies – even when they work – "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes."[162]

91. These longstanding misrepresentations minimized actual risks of long-term opioid use; they persuaded doctors and patients to discount or ignore those risks. Pharmaceutical Defendants also had to persuade them of a significant upside to long-term opioid use. But there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain."[163] In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of

[162] The New York Settlement is available at : https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf
[163] 2016 CDC Guideline. The CDC Guideline is at https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm

evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks." Despite this, Defendants falsely claimed that benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence. Not only have Defendants failed to correct these false and deceptive claims, they continue to make them today.[164]

92. These claims are not supported in the scientific literature. The 2016 CDC Guideline concluded that "there is no good evidence that opioids improve pain or function with long-term use, and . . . complete relief of pain is unlikely." (Emphasis added.) The CDC reinforced this conclusion throughout its March 15, 2016 Guideline[165]:

- "No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later . . ."
- "Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is

[164] For example, the Pharmaceutical Defendants falsely claimed that long-term opioid use improved patients' function and quality of life, including the following misrepresentations: (a) an Actavis advertisement claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives; (b) an Endo advertisement that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks, portraying seemingly healthy, unimpaired persons; (c) a Janssen patient education guide Finding Relief: Pain Management for Older Adults stated as "a fact" that "opioids may make it easier for people to live normally" such as sleeping peacefully, working, recreation, sex, walking, and climbing stairs; (d) Purdue advertisements of Oxycontin entitled "Pain vignettes" implied that Oxycontin improves patients' function; (e) Responsible Opioid Prescribing, by Cephalon, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function; (f) Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain counseling patients that opioids "give [pain patients] a quality of life we deserve"; (g) Endo's NIPC website painknowledge.com claimed that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse"; (h) Endo CMEs titled Persistent Pain in the Older Patient claimed that chronic opioid therapy had been "shown to reduce pain and improve depressive symptoms and cognitive functioning"; (i) Janssen sponsored, funded, and edited a website, Let's Talk Pain, in 2009, which featured an interview edited by Janssen claiming opioids allowed a patient to "continue to function"; (j) Purdue's A Policymaker's Guide to Understanding Pain & Its Management claimed that "multiple clinical studies" had shown opioids as effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients; (k) Purdue's, Cephalon's, Endo's, and Janssen's sales representatives conveyed and continue to convey the message that opioids will improve patient function.

[165] Fn 157, above. The CDC Guideline is at https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm

sustained and whether function or quality of life improves with long-term opioid therapy."

- "[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."

The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations."[166] As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life.[167]

93. The Pharmaceutical Defendants falsely emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. These misrepresentations by Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. The FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." The 2016 CDC Guideline describes NSAIDs, not opioids, as the first-line treatment for chronic pain, particularly arthritis and lower back pain.

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166 *Id.*

167 The 2016 CDC Guideline was not the first time a federal agency repudiated the Pharmaceutical Defendants' claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis that "[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life." In 2008, the FDA sent a warning letter to an opioid manufacturer, making it clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

94. Purdue untruthfully promoted Oxycontin as a unique opioid that provided 12 continuous hours of pain relief with one dose. Purdue knew this to be untrue and continued to make the claim as a marketing ploy. According to Purdue's research, Oxycontin wears off prior to six hours in one fourth of patients and prior to 10 hours in more than half.[168] Oxycontin tablets release about 40% of active medicine immediately. This triggers a powerful temporary response, but loses effectiveness long before the end of the dosing period. This "end of dose" failure was confirmed by the FDA as early 2010.[169] Purdue knew or should have known patients would compensate by taking more medicine more often, thereby becoming more dependent, and more prone to addiction.

95. Purdue's competitors challenged Oxycontin with better opioid release formulations. For example, Defendant ENDO sold its Opana ER as offering "real" 12-hour dosing. Purdue continued its false promotion of Oxycontin as effective for a full 12 hours and is believed to continue to do so, now, in Nebraska, and elsewhere.

96. Defendant Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA expressly limited their use to treatment of cancer pain in opioid-tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. The FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve Fentora for chronic pain because of the potential harm, including the high risk of "serious and life-threatening adverse events" and abuse – risks which are greatest in non-cancer patients.[170] The FDA issued a Public

[168] http://www.latimes.com/projects/Oxycontin-part1/ May 5, 2016.
[169] Timeline of FDA actions: https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm338566.htm
[170] Fentora action summarized at: https://www.medscape.com/viewarticle/563448

Health Advisory in 2007 emphasizing that Fentora should be used only for cancer patients who are opioid-tolerant and not for any other conditions, such as migraines, post-operative pain, or pain due to injury.[171]

97. Ignoring its legal duties, Cephalon conducted and continues to conduct sales campaigns to sell Actiq and Fentora for non-cancer, and off-label, unsafe uses. Cephalon's campaigns use subject matter experts and speakers to "teach" prescribers and provide continuing medical education credits. It uses KOLs, journal supplements, and detailing by sales representatives to enforce off-label uses and false information about the safety of Actiq and Fentora for non-cancer pain.[172] Cephalon's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were safe and effective for treating chronic pain, and approved by the FDA for such uses.[173]

98. Purdue unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. Purdue's sales representatives maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. Purdue did not report these physicians to state medical boards or law enforcement authorities as Purdue is obligated to do, and did not discontinue sales to

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171 *Id.*

172 For example: (a) Cephalon paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of *Pain Medicine News* in 2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain; (b) Cephalon's sales representatives set up speaker programs for doctors, including non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain; and (c) in December 2011, Cephalon widely disseminated a journal supplement entitled "*Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)*" to *Anesthesiology News, Clinical Oncology News,* and *Pain Medicine News* – three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain" – and not just cancer pain.

173 See, Adriane Fugh-Berman, *Off-Label Promotion, On-Target Sales,* 5 PLoS Medicine (10) e210, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2573913/

them, Purdue did use the list to persuade the FDA to bar the manufacture and sale of generic copies of the drug on the basis it was too likely to be abused. Purdue did nothing to curb diversions or abuses of Oxycontin or other opioids.

99. In an interview with the *Los Angeles Times*, Purdue's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to take action – even where Purdue employees personally witnessed the diversion of its drugs.[174] Despite its knowledge of illegal prescribing, Purdue did not report to the FDA until years after law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million Oxycontin tablets and that Purdue's district manager described it internally as "an organized drug ring."[175] Instead, Purdue protected its own profits at the expense of public health and safety. The State of New York's settlement with Purdue specifically cited the company for failing to adequately address suspicious prescribing. Yet, Purdue continues to profit from the prescriptions of such prolific prescribers including some in the Ponca Tribe's service areas.

100. Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the State of New York found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were later arrested or convicted for illegal

[174] The LA Times investigation is reported at : http://www.latimes.com/projects/la-me-Oxycontin-part2/
[175] *Id.* at pg 1, quoting Purdue Sales Manager Michele Ringler 2009 internal email.

prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct caused them to be placed on a no-call list.[176]

101. As a part of their deceptive marketing scheme, the Pharmaceutical Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the Ponca Tribe's service area and in Nebraska. For example, these Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids and therefore more likely to accept Defendants' misrepresentations.

102. The Pharmaceutical Defendants and Distribution Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain, and Native American populations who suffer known health deficiencies and risks among their populations. These Defendants targeted vulnerable patients even though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline[177] concludes that there are "special risks of long-term opioid use for elderly patients" and recommends that doctors use "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients. The same is true for veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress disorder, which interact dangerously with opioids.[178]

[176] See Fn 44.
[177] See Fn 41.
[178] *Id.*

103. The Pharmaceutical Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and deceptive. The FDA and other regulators warned these Defendants of this, and these Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths – all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. The FDA and CDC issued pronouncements that conclusively expose the known falsity of Defendants' misrepresentations. ENDO and Purdue entered agreements prohibiting them from making some of the same misrepresentations described in this Complaint in New York.[179]

104. The Pharmaceutical Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, the Pharmaceutical Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. These Defendants purposefully hid behind the projected objectivity and credibility of these individuals and organizations to vouch for the accuracy and integrity of Defendants' false statements about the risks and benefits of long-term opioid use.

105. The Pharmaceutical Defendants concealed their roles in shaping, editing, and approving information and materials disseminated by KOLs and front groups as

[179] See Fn 44.

alleged above. For example, painknowledge.org, which is run by the NIPC, did not disclose Endo's involvement. Other Pharmaceutical Defendants, such as Purdue and Janssen, ran similar websites that masked their own direct role.

106. The Pharmaceutical Defendants manipulated their self-financed, commissioned promotional materials and scientific literature to make it appear they were accurate, truthful, and supported by objective evidence. This was false. Average professional healthcare providers could not reasonably ascertain the falsity of this information. Plaintiff did not know of the existence or scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

107. The Pharmaceutical Defendants' misrepresentations deceived doctors and patients about the risks and benefits of long-term opioid use. Generally, medical doctors and patients are not aware of or do not understand these risks and benefits. Patients often report that they were not warned they might become addicted to opioids prescribed to them. As reported in January 2016, a 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told opioids were potentially addictive. This led to an FDA Safety Announcement on August 31, 2016 warning that:

> …the growing combined use of opioid medicines with benzodiazepines or other drugs that depress the central nervous system (CNS) has resulted in serious side effects, including slowed or difficult breathing and deaths. Opioids are used to treat pain and cough; benzodiazepines are used to treat anxiety, insomnia, and seizures. In an effort to decrease the use of opioids and benzodiazepines, or opioids and other CNS depressants, together, we are adding *Boxed Warnings*, our strongest warnings, to the drug labeling of prescription opioid pain and prescription opioid cough medicines, and benzodiazepines.

> Opioids are a class of powerful narcotic medicines that are used to treat pain severe enough to warrant use of an opioid when other pain medicines cannot be taken or are not able to provide enough pain relief. They also have serious risks including misuse and abuse, addiction, overdose, and death. Opioids such as codeine and hydrocodone are also approved in combination with other medicines to reduce coughing. Benzodiazepines are a class of medicines that are widely used to treat conditions including anxiety, insomnia, and seizures.
>
> We conducted and reviewed several studies showing that serious risks are associated with the combined use of opioids and benzodiazepines, other drugs that depress the CNS, or alcohol … Based on these data, we are requiring several changes to reflect these risks in the opioid and benzodiazepine labeling, and new or revised patient Medication Guides. These changes include the new Boxed Warnings and revisions to the *Warnings and Precautions, Drug Interactions, and Patient Counseling Information* sections of the labeling.
>
> We are continuing to evaluate the evidence regarding combined use of benzodiazepines or other CNS depressants with medication-assisted therapy (MAT) drugs used to treat opioid addiction and dependence. We are also evaluating whether labeling changes are needed for other CNS depressants, and will update the public when more information is available.
>
> We urge patients and health care professionals to report side effects involving opioids, benzodiazepines, or other medicines to the FDA MedWatch program….[180]

108. The Pharmaceutical Defendants' deceptive marketing scheme caused and continues to cause doctors in the Ponca Tribe's service area and in Nebraska to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia. Absent these Defendants' deceptive marketing scheme, these doctors would not have prescribed as many opioids. These Defendants' deceptive marketing schemes also caused and continue to cause patients to use opioids for their chronic pain believing they are safe and effective.

[180] 8.31.16 FDA Safety Announcement, https://www.fda.gov/Drugs/DrugSafety/ucm518473.htm

109. The escalating number of opioid prescriptions written by doctors who were deceived by the Pharmaceutical Defendants' deceptive marketing scheme produced a dramatic increase in opioid addiction, overdose, and death throughout the U.S. and Nebraska. In August 2016, the U.S. Surgeon General published an open letter to physicians nationwide, enlisting their help in this "urgent health crisis" and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, "coincided with heavy marketing to doctors… [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."[181]

110. Scientific evidence demonstrates a strong correlation between opioid prescriptions and opioid abuse. In a 2017 publication[182], the U.S. Center for Disease Control ("CDC") explained that:

> Drug overdose deaths and opioid-involved deaths continue to increase in the United States. The majority of drug overdose deaths (66%) involve an opioid. In 2016, the number of overdose deaths involving opioids (including prescription opioids and heroin) was 5 times higher than in 1999. From 2000 to 2016, more than 600,000 people died from drug overdoses. On average, 115 Americans die every day from an opioid overdose.
>
> We now know that overdoses from prescription opioids are a driving factor in the 16-year increase in opioid overdose deaths. The amount of prescription opioids sold to pharmacies, hospitals, and doctors' offices nearly quadrupled from 1999 to 2010, yet there had not been an overall change in the amount of pain that Americans reported. Deaths from prescription opioids—drugs like oxycodone, hydrocodone, and methadone—have more than quadrupled since 1999.

111. Contrary to the Pharmaceutical Defendants' misrepresentations, much opioid addiction begins with legitimately *prescribed* opioids, and therefore could have

[181] The letter may be read at https://turnthetiderx.org/#
[182] https://www.cdc.gov/drugoverdose/epidemic/index.html

been prevented had Defendants' representations to prescribers been truthful. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from pill mills, drug dealers or the internet. Numerous doctors and substance abuse counselors note that many of their patients, who misuse or abuse opioids started with legitimate prescriptions, confirming the important role that doctors' prescribing habits have played in the opioid epidemic. Opioid-related cases of NAS are rising at such a rapid pace that local governments and hospitals are unable to keep up logistically.

Distributor Defendants' Wrongful Acts

112. Manufacturer Defendants and Distributor Defendants share the responsibility for controlling the availability of prescription opioids. Opioid "diversion" occurs whenever the supply chain of prescription opioids is broken, and the drugs are transferred from a legitimate channel of distribution or use, to an illegitimate channel of distribution or use. Diversion can occur at any point in the opioid supply chain, including at the pharmacy level when prescriptions are filled for any reason other than a legitimate medical purpose.

113. At the wholesale level of distribution, diversion occurs whenever distributors allow opioids to be lost or stolen in transit, or when distributors fill suspicious orders of opioids from buyers, retailers, or prescribers. Suspicious orders include orders of unusually large size, orders that are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern, and/or orders of unusual frequency and duration.

114. Diversion occurs at the pharmacies, including whenever a pharmacist fills a prescription despite having reason to believe it was not issued for a legitimate medical purpose or not in the usual course of practice. Some signs of prescriptions issued for illegitimate medical purposes include patient prescription fills multiple times by different doctors (a/k/a doctor shopping), fills at pharmacies great distances from their residences, multiple prescriptions for the largest dose of more than one controlled substance, or when other "red flags" of warning appear. These "red flags" should trigger closer scrutiny of the prescriptions by the pharmacy. Opioids are also diverted from retail outlets when stolen by employees or others.

115. Diversion occurs through the use of stolen or forged prescriptions at pharmacies, or the sale of opioids without prescriptions, including patients seeking prescription opioids under false pretenses. Opioid diversion occurs in the United States at an alarming rate. In recent years, the number of people who take prescription opioids for non-medical purposes is greater than the number of people who use cocaine, heroin, hallucinogens, and inhalants combined.

116. The rise in heroin use is a direct result of prescription opioid diversion. The strongest risk factor leading to a heroin use disorder is prescription opioid use. In one national study covering the period 2008 to 2010, 77.4% of the participants reported using prescription opioids before initiating heroin use.[183] The CDC has reported that people

[183] https://www.cdc.gov/media/releases/2015/p0707-heroin-epidemic.html

who are dependent on prescription opioid painkillers are 40 times more likely to become dependent on heroin.[184]

117. Distributor Defendants have common law duties to exercise reasonable care under the circumstances. This involves a duty not to create a foreseeable risk of harm to others. One who engages in affirmative conduct, and thereafter realizes or should realize that such conduct has created an unreasonable risk of harm to another, is under a duty to exercise reasonable care to prevent the threatened harm.

118. Distributor Defendants are governed by the statutory requirements of the *Controlled Substances Act* ("CSA"), 21 *USC* § 801 *et seq*. and its implementing regulations and the *Nebraska Uniform Controlled Substances Act*. Distributor Defendants failed to meet the relevant standard of conduct required. The Distributor Defendants' repeated, unabashed, and prolific violations of these requirements show that they have acted in total reckless disregard.

119. By violating the CSA and the *Nebraska Uniform Controlled Substances Act* (collectively, "CSA"), the Distributor Defendants are also liable to Plaintiff under the law of Nebraska.[185] The CSA creates a legal framework for the distribution and dispensing of controlled substances. Congress passed the CSA partly out of a concern about "the widespread diversion of [controlled substances] out of legitimate channels into the illegal market."[186] CSA acts as a system of checks and balances from the manufacturing level through delivery of the pharmaceutical drug to the patient or ultimate user. Every person

[184] https://www.cdc.gov/media/releases/2015/p0707-heroin-epidemic.html
[185] See ¶ 2 of this Complaint, above. See also fn 10 above.
[186] U.S. House of Representatives, H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566, 4572.

or entity that manufactures, distributes, or dispenses opioids must obtain a "registration" with the DEA. Registrants at every level of the supply chain must fulfill their obligations under the CSA, otherwise controlled substances move from the legal to the illicit marketplace, and there is enormous potential for harm to the public.

120. All opioid distributors are required to maintain effective controls against opioid diversion. They are also required to create and use a system to identify and report downstream suspicious orders of controlled substances to law enforcement. Suspicious orders include orders of unusual size, orders deviating substantially from the normal pattern, and orders of unusual frequency. To comply with these requirements, distributors must know their customers, report suspicious orders, conduct due diligence, and terminate orders if there are indications of diversion.

121. To prevent unauthorized users from obtaining opioids, the CSA requires a distribution monitoring system for controlled substances, including registration and tracking requirements imposed upon anyone authorized to handle controlled substances. The DEA's Automation of Reports and Consolidation Orders System ("'ARCOS") is an automated drug reporting system that records and monitors the flow of Schedule II controlled substances from point of manufacture through commercial distribution channels to point of sale. ARCOS accumulates data on distributors' controlled substances, acquisition transactions, and distribution transactions, which are then summarized into reports used by the DEA to identify any diversion of controlled substances into illicit channels of distribution. Each person or entity registered to distribute ARCOS Reportable

controlled substances must report acquisition and distribution transactions to the DEA. This includes all Defendants, but they failed to report and provide:

121.1. Acquisition and distribution transaction reports must provide data on each acquisition to inventory (identifying whether it is, e.g., by purchase or transfer, return from a customer, or supply by the Federal Government) and each reduction from inventory (identifying whether it is, e.g., by sale or transfer, theft, destruction or seizure by Government agencies) for each ARCOS Reportable controlled substance. 21 *USC* § 827(d) (l); 21 *CRF* §§ 1304.33(e), (d). Inventory that is lost or stolen must be reported separately to the DEA within one business day of discovery of such loss or theft.

121.2. To maintain a complete, accurate, and current record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of. 21 *USC* §§ 827(a)(3), 1304.2l(a), 1304.22(b). It is unlawful for any person to negligently fail to abide by the recordkeeping and reporting requirements.

121.3. To maintain registration, distributors must also maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific and industrial channels.[187]

122. To combat the problem of opioid diversion, the DEA provided guidance to distributors on the requirements of suspicious order reporting in numerous venues,

[187] When determining if a distributor has provided effective controls, the DEA Administrator refers to the security requirements set forth in §§ 130 1.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion. 21 CFR § 1301.71.

publications, documents, and final agency actions. Since 2006, the DEA has conducted one-on-one briefings with distributors regarding their downstream customer sales, due diligence responsibilities, and legal and regulatory responsibilities (including the responsibility to know their customers and report suspicious orders to the DEA). The DEA provided distributors with data on controlled substance distribution patterns and trends, including data on the volume of orders, frequency of orders, and percentage of controlled vs. non-controlled purchases. The distributors were given case studies, legal findings against other registrants, and ARCOS profiles of their customers whose previous purchases may have reflected suspicious ordering patterns. The DEA emphasized the "red flags" distributors should look for to identify potential diversion.

123. Since 2007, the DEA hosted at least than five conferences to provide opioid distributors with updated information about diversion trends. The Defendant Distributors attended at least one of these conferences, which allowed for questions and discussions. The DEA has participated in numerous meetings and events with the legacy Healthcare Distribution Management Association (HDMA), now known as the Healthcare Distribution Alliance (HAD), an industry trade association for wholesalers and distributors. DEA representatives have provided guidance to the association concerning suspicious order monitoring, and the association has published guidance documents for its members on suspicious order monitoring, reporting requirements, and the diversion of controlled substances.

124. On September 27, 2006 and December 27, 2007, the DEA Office of Diversion Control sent letters to all registered distributors providing guidance on

suspicious order monitoring of controlled substances and the responsibilities and obligations of the registrant to conduct due diligence on controlled substance customers as part of a program to maintain effective controls against diversion. The September 27, 2006 letter reminded registrants that they were required by law to exercise due diligence to avoid filling orders that could be diverted into the illicit market. The DEA explained that as part of the legal obligation to maintain effective controls against diversion, the distributor was required to exercise due care in confirming the legitimacy of each and every order prior to filling. It also described circumstances that could be indicative of diversion, including ordering excessive quantities of a limited variety of controlled substances while ordering few if any other drugs; disproportionate ratio of ordering controlled substances versus non-controlled prescription drugs; the ordering of excessive quantities of a limited variety of controlled substances in combination with lifestyle drugs; and ordering the same controlled substance from multiple distributors. The letter described what questions should be answered by a customer when attempting to make a determination if the order is indeed suspicious.

125. The **Office of Diversion Control** informed the industry, including Defendants of legal requirements outlined in the September 2006 correspondence.[188] The letter reminded registrants that suspicious orders must be reported when discovered and monthly transaction reports of excessive purchases did not meet the regulatory criteria for suspicious order reporting. The letter advised registrants of their duty to perform an independent analysis of suspicious orders prior to the sale to determine if the controlled

[188] DEA Diversion Control Division Notice 2006: https://www.deadiversion.usdoj.gov/fed_regs/notices/2006/fr09062.htm

substances would likely be diverted, and to file reports of suspicious orders. The letter directed the Defendants and others, as registrants, to review DEA action addressing criteria to determine suspicious orders and obligation to maintain effective controls against diversion.

126. The Distributor Defendants' own industry group, the Healthcare Distribution Management Association, published Industry Compliance Guidelines titled "Reporting Suspicious Orders and Preventing Diversion of Controlled Substances," emphasizing the critical role of each member of the supply chain in distributing controlled substances. This fact is expressed: "At the center of a sophisticated supply chain, distributors are uniquely situated to perform due diligence in order to help support the security of controlled substances they deliver to their customers."

127. Federal regulations impose a non-delegable duty upon wholesale drug distributors to "design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 *CFR* § 1301.74(b). The Distribution Defendants, and all Defendants, failed to fulfill this duty.

128. Regulations imposing this duty have been in effect for more than 40 years. Defendants failed to comply and committed serial violations of the law for many years. The United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Division, reported that the DEA issued final decisions in 178 registrant

actions between 2008 and 2012. The Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders. These actions include the following:

128.1. On April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007,AmerisourceBergen entered into a settlement which resulted in the suspension of its DEA registration;

128.2. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

128.3. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

128.4. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

128.5. On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

128.6. On May 2, 2008, McKesson Corporation entered into an Administrative Memorandum of Agreement ("2008 MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 *CRF* § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

128.7. On September 30, 2008, Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia; Valencia, California; and Denver, Colorado;

128.8. On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center for failure to maintain effective controls against diversion of oxycodone;

128.9. On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and

128.10. On January 5, 2017, McKesson Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a $150,000,000 civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Santa Fe Springs CA, Washington Courthouse OH and West Sacramento CA.[189]

In the 2017 Settlement Agreement, McKesson expressly acknowledged that directly impacted, and occurred in, Nebraska and elsewhere.

McKesson admitted that it failed to detect and disclose suspicious orders of controlled substances, failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in its files, bypassed suspicious order reporting procedures, failed to inform the DEA Field Division offices and/or DEA Headquarters of suspicious orders of controlled substances including orders of unusual size, orders deviating substantially from normal patterns, and orders of unusual frequency as required by 21 CFR §1301.74(b), 21 U.S.C. §842(a)(5) and the 2008 agreements. It admitted these failures occurred in Nebraska and elsewhere.[190]

[189] Administrative Memorandum of Agreement between US| DOJ, DEA and McKesson Corporation effective January 17, 2017, available at https://www.justice.gov/opa/press-release/file/928476/download

[190] US DOJ DEA and McKesson Corp "Settlement Agreement and Release" executed by the United States Atty. for the District of Nebraska January for 2017, accessible at https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders

> McKesson committed a pattern of similar wrongful acts at earlier times and lied about its commitments and performance of agreements to correct and discontinue these acts.[191]

129. The Distributor Defendants admitted to the magnitude of the problem and their legal responsibilities to prevent diversion. They have made statements assuring the public they are supposedly undertaking a duty to curb the opioid epidemic.[192] These assurances, on their face, identifying and eliminating criminal activity and curbing the opioid epidemic create a duty for the Distributor Defendants to act affirmatively.

130. In addition to the obligations imposed by law, through their own declarations, representations, and affirmations, the Distributor Defendants voluntarily undertook the duty to protect the public at large against diversion from their supply chains, and to curb the opioid epidemic. The Distributor Defendants negligently failed to perform this duty. Instead, they chose to turn their backs on drug diversion to enhance sales and profits at the expense of the lives, health and well-being of the people of the United States, and the Ponca Tribe's service areas.

131. The Distributors Defendants knowingly or negligently allowed diversion. Their wrongful conduct and inaction have resulted in numerous civil fines and other

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191 In May 2008, McKesson entered into a settlement with the DEA on claims that McKesson failed to maintain effective controls against diversion of controlled substances. McKesson failed to report suspicious orders from rogue Internet pharmacies around the Country, resulting in millions of doses of controlled substances being diverted. McKesson agreed to pay a $13.25 million civil fine. McKesson also was supposed to implement tougher controls regarding opioid diversion but utterly failed to do so. McKesson's system for detecting "suspicious orders" from pharmacies was so ineffective and dysfunctional that at one of its facilities in Colorado between 2008 and 2013, it filled more than 1.6 million orders, for tens of millions of controlled substances, but it reported just 16 orders as suspicious, all from a single consumer. In 2015, McKesson was in the middle of allegations concerning its "suspicious order reporting practices for controlled substances."

192 For example, a Cardinal executive claimed that Cardinal uses "advanced analytics" to monitor its supply chain. He further extolled that Cardinal was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any *outside* criminal activity." (emphasis added).McKesson has publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders" and claimed it is "deeply passionate about curbing the opioid epidemic in our Country."

penalties recovered by state and federal agencies- including actions by the DEA related to violations of the *Controlled Substances Act*.[193]

132. Several State Boards of Pharmacy have directly disciplined wholesale distributors of prescription opioids for failure to prevent diversion, a duty recognized under state laws and regulations. These penalties have not changed their conduct. They pay fines as a cost of doing business in an industry that generates billions of dollars in revenue and profit. The Distributor Defendants have the ability and owe the duty to prevent opioid diversion, which presented a known or foreseeable risk of damage to Plaintiff

133. The Distributor and Pharmacy Defendants supplied massive quantities of prescription opioids in Nebraska with the actual or constructive knowledge that the opioids were ultimately being consumed by citizens for non-medical purposes. Many of these shipments should have been stopped or investigated as suspicious orders, but the Distributor Defendants negligently or intentionally failed to do so. Each Distributor Defendant knew or should have known that the amount of the opioids that it allowed to

[193] In 2008, Cardinal paid a $34 million penalty to settle allegations about opioid diversion taking place at seven of its warehouses in the United States. In 2012, Cardinal reached an administrative settlement with the DEA relating to opioid diversion between 2009 and 2012 in multiple states. In December 2016, a Department of Justice press release announced a multi-million dollar settlement with Cardinal for violations of the Controlled Substances Act. In connection with the investigations of Cardinal, the DEA uncovered evidence that Cardinal's own investigator warned Cardinal against selling opioids to certain pharmacies.

In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies. Again in 2012, AmerisourceBergen was implicated for failing to protect against diversion of controlled substances into non-medically necessary channels. It has been reported that the U.S. Department of Justice has subpoenaed AmerisourceBergen for documents in connection with a grand jury proceeding seeking information on the company's "program for controlling and monitoring diversion of controlled substances into channels other than for legitimate medical, scientific and industrial purposes."

flow into Nebraska was far in excess of what could be consumed for medically-necessary purposes in the relevant communities.

133.1. In 2016, the rate of opioid related overdose deaths in Nebraska was 2.4 deaths per 100,000 persons, or a diagnosed and identified 44 total opioid-related overdose deaths for the year.[194]

133.2. In 2015, 1.4 million opioid prescriptions were written in Nebraska. This was a prescribing rate of 72.8 per 100 persons, and was above the average US rate of 70 opioid prescriptions per 100 persons.[195]

133.3. The incidence of NAS in Nebraska increased eightfold between 2001 and 2013 and averaged 6.0 cases per 1000 births.[196] At least one third of these NAS births occurred in Douglas County. The number of Tribal members is not known.

134. The Distributor Defendants negligently or intentionally failed to adequately control their supply lines to prevent diversion. A reasonably-prudent distributor of Schedule II controlled substances would have anticipated the danger of opioid diversion and protected against it by, for example, taking greater care in hiring, training, and supervising employees; providing greater oversight, security, and control of supply channels. Such a distributor would have looked more closely at the pharmacists and doctors who were purchasing large quantities of commonly-abused opioids in amounts

[194] https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/nebraska-opioid-summary
[195] *Id.*
[196] *Id.* For complete analysis see, Jean Y Ko et al., *Incidence of Neonatal Abstinence Syndrome – 28 States*, Center for Disease Control & Prevention, *Weekly* (August 12, 2016) Available at: https://www.cdc.gov/mmwr/volumes/65/wr/mm6531a2.htm

greater than the populations in those areas would warrant; investigating demographic or epidemiological facts concerning the increasing demand for narcotic painkillers in the Ponca Tribe's service areas; providing information to pharmacies and retailers about opioid diversion; and following applicable statutes, regulations, professional standards, and guidance from government agencies and using a little bit of common sense.

135. Distributor Defendants made little to no effort to visit the pharmacies servicing patients in the Ponca Tribe's service areas to perform due diligence inspections to ensure that the controlled substances the Distributors Defendants had furnished were not being diverted to illegal uses. The Distributor Defendants provided to certain of their employees was affected, in part, by the volume of their sales of opioids to pharmacies and other facilities servicing the patients and citizens of the Ponca Tribe's service area, thus improperly creating incentives that contributed to and exacerbated opioid diversion and the resulting epidemic of opioid abuse.

136. It was reasonably foreseeable to the Distributor Defendants that their conduct in flooding the consumer market of the Ponca Tribe's service area and Nebraska and in the geographic area served by its hospitals with highly-addictive opioids would allow opioids to fall into the hands of children, addicts, criminals, and other unintended users. It is reasonably foreseeable to the Distributor Defendants that, when unintended users gain access to opioids, tragic preventable injuries will result, including neo-natal addiction and NAS. The Distributor Defendants knew and were deliberately indifferent to the fact that the opioids being diverted from their supply chains would create access to

opioids by unauthorized users, which, in turn, perpetuates the cycle of addiction, demand, illegal transactions, economic ruin, and human tragedy.

137. The Distributor Defendants knew or should have known that a substantial amount of the opioids dispensed to patients and citizens of the Ponca Tribe's service area and in Nebraska were being dispensed based on invalid or suspicious prescriptions. It is foreseeable that filling suspicious orders for opioids will cause harm to individual pharmacy customers, third-parties to Plaintiff.

138. The Distributor Defendants were aware of widespread prescription opioid abuse of persons who would become patients in the Ponca Tribe's service area and in Nebraska, but they nevertheless persisted in a pattern of distributing commonly abused and diverted opioids in geographic areas-and in such quantities, and with such frequency that they knew and were deliberately indifferent to the fact that abused controlled substances were not being prescribed and consumed for legitimate medical purposes.

139. If the Distributor Defendants adhered to effective controls to guard against diversion as required by law, the Plaintiff would have avoided significant damages. But, instead, the Distributor Defendants made substantial profits over the years based on the diversion of opioids affecting the Ponca Tribe's service area. Their participation and cooperation in a common enterprise has foreseeably caused damages to Plaintiff. The Distributor Defendants knew full well that Plaintiff and others would be unjustly forced to bear these injuries and damages.[197]

[197] The Court of Appeals for the District of Columbia recently issued its opinion affirming that a wholesale drug distributor does, in fact, have a duty to report all suspicious orders and also has duties beyond reporting. *Masters Pharmaceutical, Inc. v. Drug Enf't Admin*., 861 F.3d 206 (D.C. Cir. 2017).

140. The Distributor Defendants' intentional distribution of excessive amounts of prescription opioids to communities showed an intentional or reckless disregard for Plaintiff. Their conduct poses a continuing economic threat to the communities that must deal with ongoing needs of children afflicted with NAS and others afflicted by opioid addiction as adult or adolescent patients and families of those patients.

Pharmacy Defendants' Wrongful Conduct

141. Pharmacies must exercise reasonable care under the circumstances. This involves a duty not to create a foreseeable risk of harm to others. Additionally, one who engages in affirmative conduct, and thereafter realizes or should realize that such conduct has created an unreasonable risk of harm to another, is under a duty to exercise reasonable care to prevent the threatened harm.

142. Pharmacies are part of the "last line of defense" in keeping drugs from entering the illicit market. They are meant to be the drug experts in the healthcare delivery system and as such have considerable duties and responsibility in the oversight of patient care. They cannot blindly fill prescriptions written by a doctor, even one registered under the CSA to dispense opioids, if the prescription is not for a legitimate medical purpose. The CSA imposes duties and requirements on the conduct of the Pharmacy Defendant. These requirements, along with their related regulations and agency interpretations, set a standard of care for pharmacy conduct.

143. The CSA requires pharmacists to review each controlled substance prescription and, prior to dispensing medications, make a professional determination that

the prescription is effective and valid. Under the CSA, pharmacy registrants are required to "provide effective controls and procedures to guard against theft and diversion of controlled substances." 21 CFR § 1301.71(a). In addition, 21 CFR § 1306.04(a) states, "The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription."

144. Pharmacists are required to ensure that prescriptions for controlled substances are valid, and that they are issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice.

145. By filling prescriptions of questionable or suspicious origin in violation of the CSA, the Pharmacy Defendants each violated Nebraska's law as alleged herein and contributed to the cause of damages to the Plaintiff.

146. The DEA's 2010 "Practitioner's Manual" section on "Valid Prescription Requirements" instructs that "[a]n order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is an invalid prescription." Filling such a prescription is illegal. This Manual states: "The law does not require a pharmacist to dispense a prescription of doubtful, questionable, or suspicious origin. To the contrary, the pharmacist who deliberately ignores a questionable prescription when there is reason to believe it was not issued for a legitimate medical purpose may be prosecuted."[198]

[198] US DOJ, DEA Practitioner's Manual, An Informational Outline of the Controlled Substance Act, available at: https://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf

147. The DEA (as well as state pharmacy boards, national industry associations, and continuing educational programs) have provided extensive guidance to pharmacists concerning their duties to the public. The guidance teaches pharmacists how to identify red flags, which indicate to the pharmacist that there may be a problem with the legitimacy of a prescription presented by a patient. The guidance also tells pharmacists how to resolve the red flags and what to do if the red flags are unresolvable.[199] The industry guidance directs pharmacists how to recognize stolen prescription pads; prescription pads printed using a legitimate doctor' s name, but with a different call back number that is answered by an accomplice of the drug-seeker; prescriptions written using fictitious patient names and addresses, and so on. All these issues have been presented by the DEA in pharmacist training programs throughout the United States and have been used as examples by individual State Boards of Pharmacy and the National Association of Boards of Pharmacy.

148. Industry standards require pharmacists to contact the prescriber for verification or clarification whenever there is a question about any aspect of a prescription order. A pharmacist in doubt must ask for proper identification. If a pharmacist believes the prescription is forged or altered, he or she must not dispense it and the duty is to call the local police. If a pharmacist believes he or she has discovered a pattern of prescription diversion, the local Board of Pharmacy and DEA must be contacted. The Pharmacy Defendants failed to do these things.

[199] See, 81 Fed Reg No 145, p 49816 (7.28.16).

149. Standards of care for the Pharmacy Defendants are also set by applicable professional regulations in the State of Nebraska. It is a violation of professional standards not to attempt to address the suspected addiction of a patient to a drug dispensed by the pharmacist, if there is reason to believe the patient may be addicted.

150. The Pharmacy Defendants regularly filled prescriptions in circumstances where red flags were present (and sometimes many red flags). They regularly filled opioid prescriptions that would have been deemed questionable or suspicious by a reasonably prudent pharmacy. The Pharmacy Defendants have not adequately trained or supervised their employees at the point of sale to investigate or report suspicious or invalid prescriptions, or protect against corruption or theft by employees or others.

151. By failing to take adequate measures to prevent substantial opioid-related injuries that have affected Plaintiff, Pharmacy Defendants breached their duties under the "reasonable care" standard, professional duties under the relevant standards of professional practice, and requirements established by federal law under the CSA. It was foreseeable to the Pharmacy Defendants that filling invalid or suspicious prescriptions for opioids would cause harm to individual pharmacy customers, persons served the Ponca Tribe's service area that may use the wrongfully-dispensed opioids and Plaintiff's services but not pay for them. It is also reasonably foreseeable to the Pharmacy Defendants that, when unintended users gain access to opioids, preventable injuries and damages will result, including overdoses and newborns with NAS. The Pharmacy Defendants committed these acts and omissions against perosns served by Plaintiff and thereby elevated demands for Plaintiff's services.

152. The Pharmacy Defendants engaged in improper dispensing practices, and continue to do so, despite knowing full well it could take measures to substantially eliminate their complicity in opioid diversion. The Pharmacy Defendants engaged in these activities, and continue to do so, knowing full well that the Ponca Tribe would have to provide or pay for additional neo-natal medical services, emergency services, and other necessary services, and straining these communities' resources.

153. It was reasonably foreseeable to the Pharmacy Defendants that Plaintiff would be forced to bear substantial expenses and damages as a result of the Pharmacy Defendant's acts.

Additional Wrongful Acts of All Defendants

154. All Defendants participated in shared practices and actions to accomplish the common purpose of profiting from noncompliance with state and federal legal duties and committing fraud and misrepresentation with falsehoods, half-truths and omissions to the public and to healthcare providers, and violations of the law. The Defendants formed an Opioid Profiteering Enterprise and engaged in a pattern of shared racketeering activity as described above. All Defendants had, but failed to fulfill duties to disclose, reveal, monitor, identify and unmask diversion of opioids and improper uses of them, but failed to do so. Instead, they withheld and concealed known facts, misrepresented or recklessly disregarded facts and asserted others without a basis for doing so.

155. All Defendants reaped and collected unjust profits and are not entitled in equity and good faith to retain those profits. No Defendant in this opioid network would have succeeded in profiting so significantly from the opioid epidemic without the

concerted conduct of the other party, and none would have succeeded so significantly without engaging in the wrongful conduct as herein alleged. The Pharmaceutical Defendants likewise benefitted from this distribution conspiracy in that the more pervasive opioid diversion became, the more the Pharmaceutical Defendants profited. Despite access to the same information in the hands of the Distributor Defendants, the Pharmaceutical Defendants ignored warning signs of opioid diversion. As a result of the concerted actions between and among the Defendants, the Plaintiff suffered damages.

156. All Defendants conspired to conceal the truth, commit the wrongful acts, and reap the unjust profits achieved.

157. Defendants' false and deceptive statements and acts of concealment extended to Congress of the United States as well as to hospitals, physicians, State and Federal regulatory agencies, and the public at large. A May 2012 Senate Finance Committee Investigation was launched concerning narcotic pain killers. The investigation commenced because it was perceived that "an epidemic of accidental deaths and addiction resulting from the increase sale and use of powerful narcotic pain killers" was in progress. Popular brand names mentioned at the commencement of the study: Oxycontin, Vicodin and Opana.

158. The Senate Committee corresponded with Defendants, Purdue, ENDO and Johnson & Johnson, as well as others, including APF, AAM and APS and others requesting information. The correspondence sought data about the magnitude and scope of the problem, noting that "more people in the United States now die from drugs than

car accidents as a result of this new epidemic." The correspondence estimated the costs to health insurers, of up to $72.5 billion dollars annually in direct health care costs.[200]

159. While information was demanded, including information concerning influence by some or all Defendants on a 2004 Pain Guide for physicians distributed by FSMB. Questions were also posed about the influence of some or all Defendants on the APS's Guidelines and the APF's Military/Veterans/Pain Initiative. Within a short period after the investigation commenced, the APF shutdown "due to irreparable economic circumstances as noted above."

160. On March 29, 2017, another Senate investigation was launched.[201]

161. After the 2017 investigation, the Senate Committee reported that prior authorizations processes were manipulated by misleading pharmacy benefit managers about the role of certain persons and companies in the prior authorization process for product approval with the FDA. The chairman of the 2017 Senate Committee, Senator Claire McCaskill specifically reported her finding that "Opioid epidemic is the direct result of the calculated marketing and sales strategy developed in the 90's, which delivered three simple messages to physicians: First, that chronic pain was severely undertreated…; Second, the opioids were the best tool to address that pain. And third,

[200] Letter from US Senators Grassley and Baucus to Katherine Underwood, Executive Director, American Pain Society, available at https://www.finance.senate.gov/imo/media/doc/025092012%20Baucus%20Grassley%20Opioid%20Investigation%20Letter%20To%20American%20Pain%20Society.PDF

[201] Paul D. Thacker, Senators Hatch & Wyden: *Do your jobs and release the sealed opioids reports* stat News (6-27-2016), https://www.statNews.com/2016/06/27/opioid-addiction-orrin-hatch-ron-wyden/)

that opioids could treat pain without risk of serious addiction." As it turns outs, these messages were exaggerations at best and outright lies at worst.[202]

162. Researches involved in conducting studies made similar findings in 2017.[203] At the same time, the Defendants were concealing matters from Congress, they continued to seek and conceal them from the public.

Causation & Damages

163. Defendants proximately caused damages to Plaintiff. The damages they caused were foreseeable by them. Damages incurred by the Ponca Tribe are detailed below. However, damages alone are not an adequate remedy.[204]

164. Injunctive relief is necessary to prevent future diversions of opioids and to preclude future distributions of unsafe, highly addictive opioid substances by the Distribution, Pharmacy and Pharmaceutical Defendants. Injunctive relief is consistent with the *Controlled Substances Act* and its Regulations as applied to each Defendant.

165. The Ponca Tribe seeks full compensatory damages, consisting of economic damages, for costs incurred in the past and to be incurred in the future for each of the following areas or categories of damages:

165.1. Public safety expenses for exacerbated and increased personnel, equipment, facilities, space, record keeping, transportation costs and related services for crisis and emergency services, including those for

[202] HSGAC Minority Staff Report

[203] Adriane Fugh-Berman, see for summary, Adriane Fugh-Berman, et al, *Rx for Change: Obfuscating Opioids Risks*, (9/21/2017 www.nwhn.org/rx-change-obfuscating-opioid-risks/)

[204] There is no easy nationwide "fix". H Dasgupta et al, *Opioid Crisis: easy Fix to Its Social and Economic Determinants,* American Journal of Public Health (February 2018). Accessible at http://ajph.aphapublications.org/doi/abs/10.2105/ajph.2017.304187

victims of sexual assault, stalking and domestic violence, Protection Orders and enforcement, shelter placement, transportation, financial assistance, and support of partner community response teams.

165.2. Public health services expenses for exacerbated and increased personnel, equipment, facilities, space, record keeping, transportation costs and related operations for the Health Department and its personnel and its health clinics, dental clinic, and related functions and services.

165.3. Increased costs for public health services including costs for:

- First responders and emergency personnel and equipment support.
- Medications and equipment for opioid overdoses.
- Placement of addicted persons with needs for mental health care during detoxification or for mental health conditions, including inpatient and outpatient care, and treatment during incarceration.
- Juvenile intervention, protection, care, emergency care, foster care and juvenile services, and caseworkers and mental health care.
- Detoxification and related costs and services.
- Psychiatric and psychological care and services.
- Extra care associated with psychotic behavior by addicted persons.
- Housing costs including inspections, repairs, care, filling, remediating, and leasing costs due to acts of violence in residences.
- Investigation of deaths, autopsy, post mortem blood testing, and other testing, reporting and related administrative expenses.

- Other general & administration costs.

163.6 Costs incurred at the Health and Dental Clinics include

- Provider education concerning opioids.
- Tracking concerning opioid prescriptions.
- Patient monitoring and education or those using opioid prescriptions.
- Security and related precautions for opioid prescriptions.
- Security and observation for patients suspected of non-prescription opioid usage.
- Security to protect supplies of opioids to prevent diversion or theft.
- Security to protect against theft of medication from patients.
- Opioid use and risk education, monitoring and follow up for dental patients and others.
- Withdrawal care for patients with opioid addictions and co-addictions.
- Security to protect the persons served by Plaintiff's public health and safety services.
- Investigation of deaths, autopsy, post mortem blood testing, and other testing, reporting and related administrative expenses.
- Other general and administrative expenses.

166. The Ponca Tribe reasonably estimates that its annual costs associated with each and all these categories of increases exceed 15% of its budget per year. These costs are exacerbating, and are not yet fully accounted for.

167. The Ponca Tribe suffered and continues to suffer these damages directly. These losses threaten to overwhelm the Tribe's public safety, public health, law enforcement, and related health and education systems.

Legal Theories Invoked

168. The allegations above establish viable claims for compensatory economic damages for Plaintiff. They establish that damages are not an adequate remedy against future events and injunctive relief is necessary along with equitable relief to disgorge the Defendants of all unjust enrichment achieved through opioid sales.

169. The allegations above also establish that the conduct of each Defendant was deliberate, calculated, intentional and willful. This conduct occurred in direct violation of state and federal law and continued to occur both while and after all or nearly all Defendants had been punished through criminal or civil law enforcement means by the United States of America and/or its agencies and/or one or more States. Previous criminal prosecutions and civil enforcement proceedings, including fines and penalties have failed to deter the wrongful conduct of the Defendants individually and as an industry. While Nebraska law does not permit recovery of punitive damages by individual litigants, it does permit recovery of punitive for the benefit of the common school fund of the state. Plaintiff seek punitive damages in the maximum amount permitted by the law and requests that the Judgment directing the payment of these funds to the common school fund of the State of Nebraska under the direction and control of the Nebraska Board of Educational Lands & Funds. The conduct sought to be punished is

that conduct that occurred in the service area of the Ponca Tribe of Nebraska, and impacted members of the Tribe or otherwise demanded tribal services or expenditures..

170. The elements of each of the legal theories invoked below are found in the facts alleged and each of these legal theories is invoked for recovery of financial and punitive damages.

First Theory:
Violation of Ft. Laramie Treaty
"Bad Men" Clause, Art I, 15 State 635.

171. All allegations above are renewed here.

172. The Ponca Tribe of Nebraska respectfully contends that it is an intended beneficiary of the St. Laramie Treaty of 1868 negotiated between "different tribes of Sioux Indians" and "commissioners on the part of the United States.[205] The Treaty is a contract with the United States as a matter of law.[206] The Treaty contains two "bad men" provisions that read, in part:

> *If bad men among the whites*, or among other people subject to the authority of the United States, shall commit any wrong upon the person or property of the Indians, the United States will, upon proof made to the agent and forwarded to the Commissioner of Indian Affairs at Washington city, proceed at once to cause the offender to be arrested and punished according to the laws of the United States, and also reimburse the injured person for the loss sustained.

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[205] Ft. Laramie Treaty, 15 Stat 635,635 (1868). The history of the treaty is comprehensively reviewed at *United States v. Sioux Nation*, 448 U.S. 371, 374-84 (1980). The history of the Ponca Tribe's right to benefits under the Treaty is not clear from the Treaty. However, prior to 1868 the Ponca aligned with the Sioux against the Pawnee Tribe in War and, the Ponca occupied land in what are now Nebraska and South Dakota located between the Pawnee and the nomadic Sioux. The Ft. Laramie Treaty does include the lands of the Poncas in its boundaries of the "great Sioux (Lakota) Reservation. Jonathan Holmes, A Brief History of the Ponca People (July 2011)(literature survey & summary), http://www.powwows.com/a-brief-history-of-the-ponca-people/, citing and quoting multiple sources including, Dorsey, Rev. James Owen. 1890. *"The Cegiha Language". Contributions to North American Ethnology*, Vol. 6, Washington, D.C.; and, Howard, Dr. James H. 1965. *"The Ponca Tribe". Bureau of American Ethnology*, bulletin 195, Smithsonian Institution, U.S. Govt Printing Office, Washington, D.C.

[206] *Washington v. Washington State Commercial Psgr Fishing Vessel Ass'n,* 443 U.S. 658, 675 (1979).

> *If bad men among the Indians* shall commit a wrong or depredation upon the person or property of any one, white, black, or Indian, subject to the authority of the United States, and at peace therewith, the Indians herein named solemnly agree that they will, upon proof made to their agent and notice by him, deliver up the wrong-doer to the United States, to be tried and punished according to its laws; and in case they willfully refuse so to do, the person injured shall be reimbursed for his loss from the annuities or other moneys due or to become due to them under this or other treaties made with the United States.[207]

173. The Defendants are "persons" under the law as the law recognizes that corporations are persons[208]. Defendants are all "subject to the authority of the United States" as they cannot sell or distribute opioids or opioid medications without the prior express approval and authorization, and may do so only subject to the laws and regulations of the United States when permitted to do so.[209]

174. Plaintiff's claims are not under the 1st "bad men" clause and are not against the United States. Rather they arise under the 2nd "bad men" clause of the Treaty.[210] The "bad men" provisions of the Treaty are not limited to "an agent, employee, representative, or [person] otherwise acting in any other capacity for or on behalf of the United States."[211] The Treaty reaches Defendants and provides a remedy if they are found to have violated its terms because the Treaty was written to cover provocation's by all non-Indian beneficiaries of it.[212] The "bad man" provision is not confined to wrongs by government employees or representatives but the provision reaches anyone who acts

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207 *Id.* recently, the United States Court of Appeals for the Federal Circuit considered the Fort Laramie Treaty in detail at *Richard v. US*, 677 F.3d 1141 (Fed Cir 2012).

208 The corporation is a person under the law. *Citizen United v. Federal Election Com'n,* 558 U.S. 310 (2010).

209 *Food, Drug & Cosmetic Act*, 21 USC §§ 301 et seq. including § 331 (prohibited acts); § 372 (limiting authority to conduct examinations and investigations of Defendants by requiring Tribal consent); § 373 (a)(1)(Records).

210 Treaties with Indian Tribes are "construed liberally in favor of the Indians". *Okla Tax Com'n v. Chickasaw Nation*, 515 U.S. 450, 465 (1995).

211 *Richard v. US*, fn 203, 677 F3d at 1145.

212 *Id.* The Ponca Tribe contends both that the Treaty reaches Defendants and that the Treaty provides a theory of liability against them. The Tribe also contends that it is entitled to invoke the Treaty.

subject to the authority of the United States.[213] Even prolonged non-enforcement of federal law does not extinguish Indian rights under the Treaty.[214]

175. Defendants violated 21 USC § 331 in any ways as alleged above. By virtue of the wrongful acts, they are "bad men". Their conduct has been felonious, willful, intentional, and continued in flagrant disregard of its consequences. The Ponca Tribe seeks judgment against the Defendants, jointly and severally, for all compensatory and punitive damages due for each wrongful act committed in violation of the laws under which Defendants agreed to operate when they submitted applications and received approvals to manufacture, distribute, and handle Schedule II drugs including the opioids in question. The Tribe is the third-party beneficiary of these duties, and a victim of their breaches. Those breaches proximately caused the damages previously alleged.

176. Since this claim is not against the United States, there are no procedures available administratively that must be exhausted before commencement of this action.

Second Theory: Violation of Nebraska Consumer Protection Act
***Neb Rev Stat* § 59-1601 *et seq*.**

177. All allegations above are renewed here.

178. The acts, omissions and conduct of the Defendants constituted unfair, deceptive acts and practices in the conduct of the trade and commerce of manufacturing, promoting, distributing, selling, possessing, and teaching matters associated with use, of highly addictive opioid medications. The liability of the Defendants arises, in part, from direct actions and in part from underlying legal wrongs as described in the Theories

[213] *Id.*
[214] *Tsosie v. US*, 825 F.2d 393 (Fed Cir 1987).

asserted below and the facts alleged above.[215] In addition, the Defendants each engaged in acts, omissions, and conduct constituting unfair, defect acts and practice for each of the following reasons:

173.1 Each Defendant failed to establish a satisfactory and appropriate system of prescription drug monitoring to prevent misuse and insure that prescription drugs were used for medically appropriate purposes, and that the State of Nebraska remain on the cutting edge of medical information technology, and failed to do so beginning no later than August 27, 2011 when Nebraska's *Prescription Drug Monitoring* statutes went into effect.[216]

173.2 Each Defendant, as an entity described in *Neb Rev Stat* § 71-2455 or a party dealing in concert with such entity, was required to, but failed to, establish a system of prescription drug monitoring for the purposes of:

- Preventing misuse.
- Allowing and assisting prescribers and dispensers to monitor care and treatment of patients for whom a prescription drug is prescribed to insure its use for medically appropriate services.
- Insuring the State of Nebraska remains on the cutting edge of medical information technology.

[215] Plaintiff acknowledge that the *Federal Food, Drug & Cosmetic Act and the Nebraska Prescription Drug Monitoring* statutes provide no private cause of action but that acts committed in violation of them may be evidence of negligence or culpability under another theory. *See Merrell Dow Pharmaceuticals, Inc., v. Thompson*, 478 U.S. 804, 811–817 (1986), and *McElroy v. Janssen Pharmaceutica, Inc*., 2007 WL 1395585, at *1 (D Neb 2007)(Kopf, J.)

[216] *Neb Rev Stat* §71-2454 et seq.

- Reasonably and responsibly merchandising the Schedule II Controlled Substance Opioids under their care, custody and control to market.

173.3 *Neb Rev Stat* § 71-2454, requiring such a system, prescribes terms and circumstances which must be satisfied for the system to exist and operate. But Defendants did not create, maintain, or operate such a system.

173.4 The opioid medications and substances in question are drugs, medicines and medicinal substances as defined by 21 USC § 321(g) (1) and *Neb Rev Stat* § 71-2467. Each opioid medication was misbranded contrary to 21 USC § 352.

173.5 Defendants knowingly, intentionally, deliberately, and otherwise as a matter of fact, violated, repeatedly, provisions of the Nebraska *Controlled Substances Act* and thereby conducted themselves unlawfully and unreasonably.

173.6 Defendants misbranded their products and distributed them misbranded, because their package or labels bore statements designs or devices regarding their ingredients, which were false or misleading in that they failed to disclose their addictive attributes and propensity to induce addiction and co-addiction, and failed to adequately and properly advise learned intermediaries, and patients of those risks.

173.7 Defendants are believed to have caused or permitted Schedule II opioid substances to be distributed or delivered by persons not registered or authorized to do so contrary to 21 CFR §1305.06 and to have caused or

permitted them to be distributed or delivered to persons not authorized to receive them, or receiving them in such quantities and circumstances as to require reporting, but failing to report, contrary to 21 CFR §1305.16.

173.8 Defendants repeatedly represented the products to learned intermediaries including physicians that the opioids were safe, effective, and without significant or substantive risks of causing or adducing addiction even when used in accord with prescription directions.[217]

173.9 Defendants failed to disclose, and affirmatively concealed, material matters concerning directions for use of the opioid medications including risks of addiction, co-addictions, exacerbated risks when used with other additive medications, quantities, durations of administration or applications, and times thereof, all contrary to law.

173.10 Defendants sold and distributed opioids after they knew, or should have known, of the improper purpose for which the substance was to be used, or the dangers posed by it to the persons using it without adequate disclosures of those dangers.

173.11 By failing to comply with applicable provisions of federal controlled drug laws and the federal food and drug laws, and the state food drug and cosmetic laws governing the sale or distribution of controlled drugs contrary to federal law, and while concealing and misrepresenting risks associated with prescription or use of the substances.

[217] *Neb Rev Stat* § 71-2470 governs misbranding

173.12 Use of deceptive sales techniques and methodologies including use of KOL's incentives, descriptions of false conditions including "pseudo addition" and other methodologies as described above.

Third Theory: Public Nuisance & Unreasonable Interference With Right Common to General Public

174 All allegations above are renewed here.

175 The acts and conduct of the Defendants, jointly and severally, caused and created a public nuisance. Plaintiff seeks to abate the nuisance.

176 Defendants' jointly and severally misrepresented and concealed information concerning opioids as alleged above and created an epidemic in Indian Country in Nebraska and elsewhere. By doing so, they annoyed, injured, and endangered the comfort, repose, health, and safety of Plaintiff's patients, interfered with Plaintiff's relationships with its patients, and rendered Plaintiff insecure because of an increase instead of a diminution in levels of patient mortality and demands for patient care within the County's facilities. This offends decency.

177 Defendants' actions affected the entire area that Plaintiff serves..

178 Defendants have a duty to abate the nuisance but have failed to do so. On the contrary, they have denied the nuisance and denied responsibility for it and persisted, against all scientific evidence, in pressing and asserting claims that their opioid products are safe when the evidence is clearly to the contrary.

179 Defendants are liable for, and Plaintiff seeks judgment for, the financial losses and costs borne by Plaintiff as a result of the opioid epidemic and for the costs of abating the nuisance created.

Fourth Theory: Negligence

180 All allegations above are renewed here.

181 Each Defendant had a legal duty to exercise reasonable skill diligence, and prudence in connection with any, each and all levels of the process of manufacturing, testing, placing in commerce, distributing, and dispensing the opioid medications. Each also had, by engaging in the industry undertook, legal duties to prevent diversion, and to track, identify inappropriate and unusual events, and protect the public from unlawful or inappropriate diversion of opioid medications, excessive and extraordinary purchasers with purchases beyond reasonable means and bounds, and extraordinary and unusual prescribers making prescriptions in excess of reasonable means and bounds. They also failed to account for and collect unused medications, protect sample supplies, and prevent excessive opioid medications from flooding the market. Instead of doing so, each Defendant breached these duties. The acts and omissions of the Defendants constituting negligence are more fully plead above. They are summarized here:

181.3 Failure to warn foreseeable users of risks of addiction, or conscious or reckless disregard of the risks and the foreseeability of it.

181.4 Misrepresentation of risks of addiction, or conscious or reckless disregard of the risks.

181.5 Concealment of material facts known about risks of addiction, or conscious or reckless disregard of the truthful known circumstances.

181.6 Misrepresentation of the known facts concerning the limited or unproven value of the opioids for treatment of cancer-related and other pain.

181.7 Misrepresentation of opinions of opinion leaders who allegedly had experiences, or using them to misstate deceptive claims of Defendants concerning risks and benefits.

181.8 Failure to establish tracking systems and track distribution to prevent diversion, identify probable diversion, identify probable abusive prescribers or criminal elements and failure to report them to authorities as required, or conscious or reckless disregard of the circumstances.

181.9 Failure to reasonably commercialize their opioid products with reasonable, prudent disclosures of the kind made by reasonable, prudent manufacturers, distributors or pharmacies.

181.10 Failure to maintain effective controls against diversion of controlled substances, or conscious or reckless disregard of the circumstances.

181.11 Marketing through unbranded advertising that promoted opioid use generally, yet silent was to a specific opioid, and was misrepresented to create the appearance of third-party promotion, or conscious or reckless disregard of the circumstances in which such advertising occurred.

181.12 Failure to disclose known facts while promoting Oxycontin as a unique opioid that provided 12 continuous hours of pain relief with one dose and

untruthfully promoting other opioids making false or misleading continuous hours of pain relief claims as marketing ploys, or conscious or reckless disregard of the circumstances.

181.13 Failure to heed DEA and FDA and CDC warnings, advisories and letters to all registered distributors providing guidance on suspicious order monitoring of controlled substances and the responsibilities and obligations of the registrant to conduct due diligence on controlled substance customers as part of a program to maintain effective controls against diversion, or conscious or reckless disregard of the circumstances.

181.14 Failure to disclose that the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use, or conscious or reckless disregard of the circumstances.

181.15 By the Distributor Defendants, aided by all others, negligent or intentional failed to adequately control their supply lines to prevent diversion, or conscious or reckless disregard of the circumstances.

181.16 As registrants responsible for Schedule II controlled substances, failure to anticipate the danger of opioid diversion and protect against it in hiring, training, and supervising employees and providing oversight, security,

and control of supply channels, or conscious or reckless disregard of the circumstances.

181.17 Failure to disclose results of and concealment of known facts like those learned eventually with results like those of the National Institute on Drug Abuse-funded study found treatment with extended-release naltrexone reduced relapse rates among criminal justice-involved adults with a history of opioid dependence.

181.18 Negligent or reckless promotion of false information concerning drug trials, clinical histories and observations concerning dangers of opioid uses, and limited benefits of opioid usage

181.19 Negligent or reckless disregard for the dramatic can't inexplicable rates of consumption of the product by certain patients or patient groups, or prescribers, and failure to report.

181.20 Negligence per se for violation of statutory and regulatory duties as alleged above.

181.21 Negligent use of unbranded advertisements, third parties, and front groups, all as alleged above, to disguise the sources of their fraudulent statements, increase the effectiveness of their misinformation campaign.

181.22 Violation of provisions of the Nebraska *Controlled Substances Act* and thereby conducting themselves unlawfully and unreasonably as alleged throughout this Complaint.

181.23 Other acts of negligence requiring discovery.

182 Defendants violated the regulations and responsibilities imposed upon them by State and Federal law as described above, and did so knowingly, intelligently, voluntarily and in utter disregard for the safety of the public. As a result, the Defendants each committed of negligence *per se*.

183 As a direct, proximate result and foreseeable consequence of the acts and omissions of each Defendant, they proximately caused Plaintiff's damages. Defendants are jointly and severely liable for those damages.

Fifth Theory: Fraudulent Misrepresentation and Fraudulent Concealment

184 All allegations above are renewed here.

185 Defendants' acts and conduct, as described above were intentional, willful and deliberate where so alleged. In many instances, as alleged, these acts were criminal, and constitute willful, active deception and fraud. The statements falsely made, and the information falsely concealed, and the plan to dupe the medical public and patients, were all fraudulent, deceptive, and deceitful. Included the acts and omissions described above, and with respect to certain Defendants above, as alleged.

186 The false representations and concealments made by each and all Defendants, and joined in and supported by each and all Defendants through their conspiracy, proximately caused the damages Plaintiff seeks to recover. The did so to induce reliance by the public, including Plaintiff and those it serves, relied, reasonably on the material, false statements, representations and assurances of Defendants about the opioid medications they designed, manufactured, distributed and dispensed, though the Defendants knew, or should have known, those statements were false. Plaintiff had no

way to learn the falsity of these statements and was compelled to rely upon them. They did so reasonably. Their reliance was justified.

187 The damages sustained by Plaintiff were a direct, proximate result of the reasonable reliance on each Defendants false, deceptive and misleading statements. If any of the Defendants had broken ranks with the others and been truthful and been public about their truthfulness, there is substantial probability that the fraudulent acts of all others would have been discovered. Therefore, by their silence and knowing and conscious refusal to speak, each Defendant caused and contributed to the cause of the losses and damages sustained.

Sixth Theory: Lanham Act, 15 USC § 1125(a)(1)(B)

188 All allegations above are renewed here.

189 Each Defendant, as manufacturer or distributor, in its capacity in one manner or another, did, in connection with opioid medications and their manufacturer, testing, introduction into commerce, distribution and delivery, use words, terms, names, symbols and devices, as well as combinations thereof, as well as false and misleading descriptions of fact and false or misleading representations of the products, all in violation of 15 USC § 1125(a)(1)(B). They did each further do so in commercial advertising or promotions in which they misrepresented the nature, characteristics, and qualities of the opioid medications in violation of 15 USC § 1125(a)(1)(B).

190 By reason of these acts and omissions, Defendants are jointly and severally liable in this civil action for all damages proximately caused to Plaintiff.

191 As alleged above, the manufacturing Defendants, distributor Defendants, and pharmacy Defendants, each and all committed the deceptive advertising, promotional, and representational actions described above.

192 Plaintiff is entitled to legal and equitable relief, including disgorgement of profits, compensatory damages, and, to abate the risk and threat of ongoing behaviors which are still unabated by the Defendants, injunctive relief to prevent recurrence.

Seventh Theory: *Racketeer Influenced & Corrupt Org. Act,* 18 USC §§ 1961 *et seq*.

193 All allegations above are renewed here.

194 The conduct of the Defendants, and their continuing conduct, has occurred through legitimate and illegitimate means. The Defendants formed an association-in-fact enterprise and, within and among them, individual enterprises which, in turn, joined their larger association-in-fact enterprise. At all relevant times, each Defendant was a "person" for purposes of 18 USC § 1961 (3) because each entity was capable of holding and did hold, legal and beneficial interests and property.

195 For more than ten (10) years, Defendants aggressively sought to sell their dangerous products, enhance revenues and profits, and achieve increasing volumes of sales of opioid medications, though the quantity sold were so obviously in excess of the amounts required by the American public as to inform any reasonable and prudent person of the risks and dangers of continuing to authorize or permit the sale of the goods.

196 Defendants were each "registrants" within the meaning of the Controlled Substances Act, as each sold or dealt with Schedule II Controlled Substances.

Accordingly, each had a duty to create and maintain effective controls against diversion, to design and operate systems to identify suspicious orders and terminate sales to suspicious customers, and to report suspicious circumstances to the DEA. They were also obligated to make sales within limited quotas thereafter set by the DEA.

197 The system created by the *Controlled Substances Act*, including the establishment of quotas, was specifically designed to reduce or eliminate diversion of Schedule II Controlled Substances including opioids. But, the system required compliance by Defendants.

198 Defendants were unable to achieve increasing sales as desired by complying with the law. They therefore embarked upon systematic, fraudulent, misleading acts and acts of concealment in violation of their statutory, regulatory and common law duties to maintain effective controls against diversion, design and operate systems to identify suspicious orders, halt unlawful sales and to notify the DEA of suspicious activity. Upon failing to do so, and maintaining this failure, Defendants repeatedly engaged in unlawful sales of opioids and, in turn, artificially and illegally increased the quantities of opioids in circulation far beyond permissible levels as established by the DEA.

199 The Defendants engaged in a scheme to achieve the foregoing things. The scheme was carried out through their association-in-fact. It was born of the remarkable demand for opioids by persons addicted. Upon observing and discovering this Defendants continued to sell and promote the medications rather than to hold them or refrain from sale. As a direct, proximate result of this scheme, Defendants extracted

billions of dollars in revenue from hospitals, including Plaintiff, and from other organizations and caused dramatic adverse consequences and foreseeable damages to them all as alleged.

200 Alternatively, Defendants were also members of a legal enterprise. They belonged to the Health Care Distribution Alliance, a distinct legal entity, qualifying as an enterprise under 18 USC § 1961 (4). Each Defendant, in one manner or another, is believed to have been a member participant, sponsor or other supporter of the Health Care Distribution Alliance. HDA was used by the Defendants to conduct their RICO Enterprise. Each Defendant is a legal entity separate from the alliance.

201 The alliance the operated on terms diametrically contrary to the purpose and intent of the *Controlled Substances Act* and its closed system designed to assure the identification and prevention of diversion.

202 The quota system was a central and basic element of the closed system. It applies to Schedule I and Schedule II Controlled Substances and did at all relevant times.

203 Defendants operated as an association in fact to improperly and illegally increase sales and revenues to unlawfully increase quotas above levels set by the DEA and, in turn, to collectively profit from manufacturing distribution of greater and greater pools of opioids each year. Each member of the RICO Enterprise participated in the conduct of the enterprise including patterns of racketeering activity. Each shared remarkable profits generated by the scheme.

204 Defendants engaged in lobbying efforts against DEA use of authority to investigate and hold parties responsible for wrongful acts. Congress passed the *Ensuring*

Patient Access and Effective Drug Enforcement Act, but it was thwarted by DEA's inability to issue orders to show cause and to suspend or revoke registrations.

205 The pain management forum, a front organization for Defendants, and its members poured millions of dollars into lobbying efforts while the HDA devoted only a reasonable sum for this purpose.

206 The RICO Enterprise functioned by selling prescription opioids in interstate commerce.

207 Each Defendant communicated with the other Defendants and with others in the chain of distribution on a regular basis by participating in joint lobbying efforts, trade industry organizations and contractual relations, sharing of information, observation of activities and behaviors at the market place, and in other means. In 2006 through 2015 Defendants worked together through pain care forum to spend over $740 million in lobbying across the United States. These funds were used to enable and operate the RICO Enterprise.

208 Defendants disseminated false and misleading statements to the public regarding the safety of prescription medication. They also falsely disseminated statements assuring their compliance with obligations to protect the public against theft, diversion, over-prescriptions, mis-prescriptions and false information about opioid medications producing over-prescription and addiction.

209 Defendants failed and refused to identify, investigate or report suspicious activities of the market place, including failure to identify and report drug diversion rings about which they had actual knowledge. They worked together to insure that opioid

production quotas continued to increase allowing them to generate more and more profits from their illegal enterprise.

210 Defendants as RICO scheme participants engaged in intentional steps to conceal their scheme. They used unbranded advertisements, third parties, front groups, all as alleged above, to disguise the sources of their fraudulent statements, increase the effectiveness of their misinformation campaign, deceive hospitals, doctors and patients, sell more and dangerous quantities of opioid and ignore the needs of the American population for them by flooding the market.

211 Each time a participant in the RICO scheme distributed a false statement by mail or wire, it committed a separate act of mail or wire fraud contrary to 18 USC §§ 1341 and 1342 respectively.

212 Each Defendant used thousands of pieces of interstate mail and thousands of interstate wire communications and email to accomplish their misrepresentations, concealments, false and material omissions, and deceptions concerning opioid products. Defendants engaged in a continuous pattern of doing so for a decade or longer. The pattern was one of racketeering activity intentionally committed and participated in, by each Defendant.

213 Each Defendant conducted and participated in a pattern of racketeering activity by engaging in or promoting and supporting felonious manufacturer importation receipt concealment, purchase and sale, as well as other dealings, in one or more control substances on terms punishable under the laws of the United States including 21 USC § 483 (a)(4). This statute makes it unlawful for any person to knowingly or intentionally

furnish false information or omit material information from any application, report, record, or other document required to be made kept or filed under Federal law. Each instance constitutes a crime and specifically a felony.

214 Each Defendant was a registrant as alleged and required to do the things described above. Each Defendant knowingly and intentionally failed and refused to do so and conspired with the others to conceal, and accomplish their scheme.

215 As a direct, proximate result Plaintiff sustained damages as alleged.

216 Pursuant to 18 USC § 1964 (c) Plaintiff is entitled to recover treble damages, attorney's fees, and all costs incurred in defense of this litigation.

217 The threat of ongoing conduct by Defendants is present and unabated. Indeed, one or more Defendants engaged in similar patterns of illegal activity involving other drugs on earlier occasions and paid hundreds of millions, and even billions, of dollars of fines. But, these facts did not alter the circumstances and did not prevent Defendants from committing the wrongful acts in question again. Specifically, Johnson & Johnson, engaged in virtually identical false and conspiratorial activity in connection with the sale of psychotropic drugs, including, but not limited to, Risperdol. So did others though discovery is required. The period of time during which Johnson & Johnson engaged in that unlawful activity over lapped the period of time in question in this case.

218 There is a grave and immediate threat of continuing and ongoing wrongful conduct and harm by the Defendants. This is proven by their past convictions massive fines and penalties, Regulatory Agreements, and continuing patterns of wrongful acts.

An adequate remedy at law does not exist to prevent the damages that will arise if this occurs. Accordingly, injunctive relief is necessary.

Eighth Theory: Unjust Enrichment

219 All allegations above are renewed here.

220 Each Defendant received benefits in the form of hundreds of millions and in some instances perhaps billions of dollars in revenue from the sale of prescription opioid medications. The precise amounts derive by each Defendant require discovery.

221 Defendants were each aware of these benefits and their receipt as a result of their conduct, described above, and each designed that conduct to cause and bring about the continuing accrual of the benefit to each of them.

222 Defendants retained the benefits at the expense of Plaintiff and others who have born, and continue to bear, the costs of Defendants' scheme.

223 It would be unjust and inequitable for Defendants to be permitted to retain the benefits of their scheme without paying a) all costs incurred by Plaintiff as a proximate result of the acts and omissions of the Defendants; b) all costs incurred by Plaintiff to acquire the opioid medications in the course of its hospital activities; c) disgorgement of all profits made by each Defendant; d) attorney's fees and costs to the extent permitted by law; and, e) punitive damages in an amount equal to not more than 10x the amount of the compensatory damages awarded because the conduct was intentional, willful, and in utter disregard of Defendants duties and public safety.

Ninth Theory: Civil Conspiracy

224 All allegations above are renewed here.

225 The Defendants agreed to, either explicitly or by joining and copying the actions of one another's and doing so implicitly, engage in a campaign to overwhelm the market with false, deceptive, misleading information about a) opioid medications; b) the safety of opioid medications for use to treat chronic pain; c) the improbability and low incidents of addiction to opioid medications; d) the symptoms of opioid addiction which Defendants endeavor to and did persuade much of the medical community were signs of a condition they falsified and created for rhetorical purposes, and called pseudo-addiction; e) falsely promoted research that actually never occurred; and, f) engaged key opinion leaders and essentially bribed them to make false testimonials, statements and by doing so to impact and alter the standard of care.

226 Plaintiff was directly, proximately harmed as a result of the civil conspiracy and underlying wrongful acts committed by the Defendants. The Defendants are jointly and severally liable for all damages and losses for the separate distinct, and common and collective, contributions made my each to their conspiracy.

Requests for Relief

On the foregoing basis Plaintiff requests Judgment for:

227 All damages actually incurred by Plaintiff. Judgment for this sum is sought under each legal theory asserted above.

228 All damages recoverable, including treble damages, and attorneys' fees under 18 USC § 1962 *et seq*.

229 Actual compensatory, and punitive, damages as authorized by Nebraska law under Plaintiff's fraud theories with punitive damages to be paid to the Common

School Fund to the extent awarded under Nebraska law, for the benefit of the public schools of Nebraska.

230 Judgment for all sums recoverable for violation of 15 USC § 1125 (a) including costs and attorney's fees.

231 Injunctive relief to enjoin each Defendant and its officers, directors, agents, successors and employees, parents, subsidiaries, or sibling entities, and all other persons acting in concert with them from engaging in the continuing and ongoing pattern of wrongful activity and wrongful acts described above.

232 Other relief as authorized by law.

Jury Demand. Trial Location Designation.

Plaintiff demands trial by jury. Plaintiff designates Omaha, Nebraska as the location for trial.

Ponca Tribe of Nebraska, Plaintiff

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